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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 579

[Docket No. FDA–2012–F–0178]

Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Electron Beam and X-Ray Sources for Irradiation of Poultry Feed and Poultry Feed Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for irradiation of animal feed and pet food to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients. This action is in response to a food additive petition filed by Sadex Corp.

DATES: This rule is effective May 10, 2013. Submit either electronic or written objections and requests for a hearing by June 10, 2013.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2012–F–0178, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

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

Written Submissions

Submit written objections in the following ways:

Mail/Hand delivery/Courier (For paper, disk, or CD–ROM 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 Agency name and [Docket Number] for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections 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: Isabel W. Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, *isabel.pocurull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of February 29, 2012 (77 FR 12226), FDA announced that a food additive petition (animal use) (FAP 2272) had been filed by Sadex Corp., 2650 Murray St., Sioux City, IA 51111. The petition proposed to amend Title 21 of the Code of Federal Regulations (CFR) in part 579 *Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food* (21 CFR part 579) to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. One comment was received that was not substantive.

II. Conclusion

FDA concludes that the data establish the safety and utility of electron beam and x-ray sources for use as proposed with modification and that the regulations for irradiation of animal feed and pet food should be amended as set forth in this document.

III. Public Disclosure

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

IV. Environmental Impact

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

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections by (see DATES). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 579

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 579 is amended as follows:

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

■ 1. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

■ 2. In § 579.40, revise paragraph (a) to read as follows:

§ 579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.

* * * * *

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of cobalt-60 or cesium-137;

(2) Electrons generated from machine sources at energy levels not to exceed 10 million electron volts;

(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts, except as permitted by § 179.26(a)(4) of this chapter; or

(4) X-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

* * * * *

Dated: April 22, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–11147 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0328]

RIN 1625–AA00

Safety Zone; Melrose Pyrotechnics Fireworks Display; Chicago Harbor, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Michigan in Chicago Harbor, Chicago Illinois. This safety zone is intended to restrict vessels from a portion of Chicago Harbor due to a Fireworks display. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the fireworks display.

DATES: This rule is effective from 5 p.m. on May 18, 2013, until 11:59 p.m. on June 11, 2013. This rule will be enforced from 5 p.m. until 11:59 p.m. on May 18 and June 11, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2013–0328. 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 temporary rule, contact or email MST1 Joseph McCollum, U.S. Coast Guard Sector Lake Michigan, at 414–747–7148 or *Joseph.P.McCollum@uscg.mil.* If you have questions on viewing the docket, call Barbara Hairston, 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
TFR Temporary Final Rule

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 (NPRM) 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 both impracticable because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with a maritime fireworks display, which are discussed further below.

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 and contrary to the public interest.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish regulated navigation areas and limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

During the evenings of May 18 and June 11, 2013, Melrose Pyrotechnics will launch a fireworks display from the break wall south of Navy Pier in Chicago Harbor, Chicago, IL. The Captain of the Port, Lake Michigan, has determined that these fireworks displays will pose a significant risk to public safety and property. Such hazards include falling debris and collisions among spectator vessels.

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 spectators and vessels during the fireworks displays within Chicago Harbor. This zone will be effective from 5 p.m. on May 18, 2013, until 11:59 p.m. on June 11, 2013. This zone will be enforced during the fireworks displays between 5 p.m. until 11:59 p.m. on May 18 and June 11, 2013. This zone will encompass all waters of Lake Michigan, Chicago Harbor within an 800 foot radius of an approximate launch position at 41°53′18.0″ N, 87°36′11.8″ W (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Lake Michigan, or his designated on-scene representative. The Captain of the Port or his 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. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

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 small and enforced for only one day in May and one day in June. 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

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. 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 will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Chicago Harbor on May 18 and/or June 11, 2013.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This safety zone would be effective and thus subject to enforcement, for only one day in May and one day in June. Traffic may be allowed to pass through the zone with the permission of the Captain of the Port. The Captain of the Port can be reached via VHF channel 16. Before the enforcement of the zone, we would issue local Broadcast Notice to Mariners.

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** section 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**.

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; 46 U.S.C. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0328 to read as follows:

§ 165.T09–0328 Safety Zone; Melrose Pyrotechnics Fireworks Display; Chicago Harbor, Chicago, Illinois.

(a) *Location.* The safety zone will encompass all waters of Lake Michigan, Chicago Harbor within an 800 foot radius of an approximate launch position at 41°53′18.0″ N, 87°36′11.8″ W (NAD 83).

(b) *Effective and Enforcement Period.* This rule is effective from 5 p.m. on May 18, 2013, until 11:59 p.m. on June 11, 2013. This zone will be enforced with actual notice from the on-scene Captain of the Port representative during the fireworks displays between 5 p.m. until 11:59 p.m. on May 18 and June 11, 2013.

(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 his 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 his 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 behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Lake Michigan or his on-scene representative to obtain permission to do so. The Captain of the Port, Lake Michigan or his 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 his on-scene representative.

Dated: April 30, 2013.

M.W. Sibley,

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

[FR Doc. 2013–11135 Filed 5–9–13; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 13–905; MB Docket No. 12–53; RM–11658]

Radio Broadcasting Services; Dermott, Arkansas, and Cleveland, Mississippi

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Delta Radio Network, LLC, substitutes FM Channel 224A for 289A at Dermott, Arkansas, and substitutes FM Channel 226C2 for vacant 225C2 at Cleveland, Mississippi, as part of a contingently filed ''hybrid'' application and rule making petition. The purpose of the proposed channel substitutions is to accommodate the application to upgrade WIBT–FM at Indianola from Channel 288A to Channel 289C2. *See* FCC File No. BPH–20110913AAK. Channel 224A can be allotted at Dermott with a site restriction of 3.5 km (2.2 miles) southeast of city reference coordinates. The reference coordinates for Channel 224A at Dermott are: 33–30–23 NL and 91–24–19 WL. Channel 226C2 can be allotted at Cleveland, Mississippi, with a site restriction of 25.4 km (15.8 miles) northwest of city reference coordinates. The reference coordinates for Channel 226C2 at Cleveland are: 33–55–25 NL and 90–53–40 WL. *See* Supplementary Information *infra.*

DATES: Effective June 10, 2013.

FOR FURTHER INFORMATION CONTACT: Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 12–352, adopted April 25, 2013, and released April 26, 2013. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *www.bcpiweb.com.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506 (c)(4). The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

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

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

§ 73.202 [Amended]

■ 2. In § 73.202(b):

■ a. The Table of FM Allotments under Arkansas is amended at Dermott by

removing Channel 289A and by adding Channel 224A.

■ b. The Table of FM Allotments under Mississippi is amended at Cleveland by removing Channel 225C2 and by adding Channel 226C2.

[FR Doc. 2013–11123 Filed 5–9–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 76

[MM Docket No. 00–10; FCC 01–123 and MM Docket No. 93–215; FCC 95–502]

Establishment of Class A TV Service and Cable Television Rate Regulation; Cost of Service Rules—Clarification Regarding Information Collection Requirements; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule; clarification document published at 78 FR 12967 on February 26, 2013. This document corrects several references in the rule to read ''47 CFR 76.922(i)(6)(ii) through (viii).''

DATES: Effective May 10, 2013.

FOR FURTHER INFORMATION CONTACT: Shirley Suggs, 202 418–1568, Media Bureau.

SUPPLEMENTARY INFORMATION: The Commission published a document in the **Federal Register**, 78 FR 12967 on February 26, 2013, clarifying the effective date of rules. This document corrects several CFR references.

Correction

1. On page 12968, in the first column, in the **DATES** section, ''47 CFR 76.922(i)(6)(i) and (i)(7)'' is corrected to read ''47 CFR 76.922(i)(6)(ii) through (viii)''.

2. On page 12968, in the second column, under **SUPPLEMENTARY INFORMATION**, ''47 CFR 76.922(i)(6)(i) and (i)(7)'' is corrected to read ''47 CFR 76.922(i)(6)(ii) through (viii)''.

3. On page 12968, in the third column, under **SUPPLEMENTARY INFORMATION**, ''76.922(i)(6)(i) and (i)(7)–61 FR 9367, March 8, 1996'' is corrected to read ''76.922(i)(6)(ii) through (viii), March 8, 1996''.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–10981 Filed 5–9–13; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 78, No. 91
Friday, May 10, 2013

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.

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2013–0013]

RIN 3170–AA37

Loan Originator Compensation Requirements Under the Truth In Lending Act (Regulation Z); Prohibition on Financing Credit Insurance Premiums; Delay of Effective Date

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Proposed rule with request for public comment.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is proposing to temporarily delay the June 1, 2013, effective date of a prohibition on creditors financing credit insurance premiums in connection with certain consumer credit transactions secured by a dwelling. The prohibition was adopted in the Loan Originator Compensation Requirements under the Truth in Lending Act (Regulation Z) Final Rule, issued on January 20, 2013. Temporary delay of the effective date would permit the Bureau to clarify, before the provision takes effect, its applicability to transactions other than those in which a lump-sum premium is added to the loan amount at closing.

DATES: Comments must be received on or before May 25, 2013.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2013–0013 or RIN 3170–AA37, by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail/Hand Delivery/Courier:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552.

Instructions: All submissions should include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect the documents by telephoning (202) 435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or social security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Richard Arculin or Daniel Brown, Counsels, Office of Regulations, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Background

In January 2013, the Bureau issued several final rules concerning mortgage markets in the United States, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). Public Law 111–203, 124 Stat. 1376 (2010). One of these final rules was the Loan Originator Compensation Requirements under the Truth in Lending Act (Regulation Z) Final Rule (''Final Rule'').[1] The Final Rule implemented Dodd-Frank Act amendments to the Truth in Lending Act (TILA) addressing loan originator compensation; qualifications of, and registration or licensing of loan originators; compliance procedures for depository institutions; mandatory arbitration; and the financing of single-premium credit insurance. With regard to the financing of single-premium credit insurance, the Final Rule included a provision implementing the Dodd-Frank Act section 1414 amendment that added new TILA section 129C(d), 15 U.S.C. 1639c(d). That provision prohibits creditors from financing premiums or fees for certain credit insurance products in connection with certain consumer credit transactions secured by a dwelling. The Bureau implemented this provision by adopting § 1026.36(i).

A. Title XIV Rulemaking Effective Dates

In enacting the Dodd-Frank Act, Congress significantly amended the statutory requirements governing a number of mortgage practices, including loan originator compensation. Under the statute, most of these new requirements would have taken effect automatically on January 21, 2013, if the Bureau had not issued implementing regulations by that date.[2] To avoid uncertainty and potential disruption in the national mortgage market at a time of economic vulnerability, the Bureau issued several final rules (''the Title XIV Rulemakings'') in January 2013, including the Final Rule issued on January 20, 2013, to implement these new statutory provisions and provide for an orderly transition. To allow the mortgage industry sufficient time to comply with the new rules, the Bureau established January 10, 2014—one year after issuance of the earliest of the Title XIV Rulemakings—as the baseline effective date for most of the Title XIV Rulemakings, including most provisions of the Final Rule. However, the Bureau identified certain provisions that it believed did not present significant implementation burdens for industry, including § 1026.36(h) on mandatory arbitration clauses and waivers of certain consumer rights and § 1026.36(i) on financing single-premium credit insurance, as adopted by the Final Rule. For these provisions, the Bureau set an earlier effective date of June 1, 2013.

B. Implementation Initiative for New Mortgage Rules

On February 13, 2013, the Bureau announced an initiative to support implementation of its new mortgage rules (Implementation Plan),[3] under which the Bureau would work with the mortgage industry to ensure that the new rules can be implemented accurately and expeditiously. The Implementation Plan included (1) coordination with other agencies; (2) publication of plain-language guides to

[1] 78 FR 11279 (Feb. 15, 2013).

[2] Dodd-Frank Act section 1400(c), 15 U.S.C. 1601 note.

[3] Consumer Financial Protection Bureau Lays Out Implementation Plan for New Mortgage Rules. Press Release. Feb. 13, 2013.

the new rules; (3) publication of additional corrections, adjustments, and clarifications of the new rules, as needed; (4) publication of readiness guides for the new rules; and (5) education of consumers on the new rules. This proposal is a proposed adjustment to the new rules. The purpose of these updates is to address important questions raised by industry, consumer groups, or other agencies.

II. Legal Authority

On July 21, 2011, section 1061 of the Dodd-Frank Act transferred to the Bureau the ''consumer financial protection functions'' previously vested in certain other Federal agencies, including the Board of Governors of the Federal Reserve System. The term ''consumer financial protection function'' is defined to include ''all authority to prescribe rules or issue orders or guidelines pursuant to any Federal consumer financial law, including performing appropriate functions to promulgate and review such rules, orders, and guidelines.'' 12 U.S.C. 5581(a)(1). TILA is a Federal consumer financial law. Dodd-Frank Act section 1002(14), 12 U.S.C. 5481(14) (defining ''Federal consumer financial law'' to include the ''enumerated consumer laws'' and the provisions of title X of the Dodd-Frank Act); Dodd-Frank Act section 1002(12), 12 U.S.C. 5481(12) (defining ''enumerated consumer laws'' to include TILA). Accordingly, the Bureau has authority to issue regulations pursuant to TILA.

As amended by the Dodd-Frank Act, TILA section 105(a), 15 U.S.C. 1604(a), directs the Bureau to prescribe regulations to carry out the purposes of TILA, and provides that such regulations may contain additional requirements, classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions, that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance. Further, under Dodd-Frank Act section 1022(b)(1), 15 U.S.C. 5512(b)(1), the Bureau has general authority to prescribe rules as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof. The Bureau is proposing to temporarily delay the effective date pursuant to its TILA section 105(a) and Dodd-Frank Act section 1022(b)(1) authority. The Bureau believes such a delay will facilitate compliance and help ensure that the Final Rule does not have adverse unintended consequences.

III. Effective Date

As discussed above, Dodd-Frank Act section 1414 added TILA section 129C(d), which generally prohibits a creditor from financing any premiums or fees for credit insurance in connection with any residential mortgage loan or with any extension of credit under an open end consumer credit plan secured by the consumer's principal dwelling.[4] The prohibition applies to credit life, credit disability, credit unemployment, credit property insurance, and other similar products. The same provision states, however, that the prohibition does not apply to credit insurance for which premiums or fees are calculated and paid in full on a monthly basis or to credit unemployment insurance for which the premiums are reasonable, the creditor receives no compensation, and the premiums are paid pursuant to a separate insurance contract and are not paid to the creditor's affiliate.

The Bureau proposed to implement this provision through § 1026.36(i), which generally tracks the statutory language. In the proposal, the Bureau stated its belief that the provisions were generally straightforward, but sought comment on whether any issues raised by the provision required clarification. Anticipating that few, if any, clarifications would be necessary and that accordingly industry would not require significant time to accommodate any clarifications of the final rule, the Bureau also sought comment on whether the provision should become effective sooner than January 2014.[5]

The Bureau received very few public comments on the substance of the proposed prohibition or the earlier effective date. Consumer groups sought clarification on the provision's applicability to certain factual scenarios where credit insurance premiums are charged periodically, rather than as a lump-sum added to the loan amount at closing. They also urged the Bureau to provide an early effective date for the provision. The Bureau did not receive any public comments from the credit insurance industry. The Bureau received some limited comments from creditors concerning the general prohibition, but these comments did not address the applicability of the provision to transactions in which premiums are charged periodically. In the preamble to the Final Rule, the Bureau provided some explanation concerning the provision's applicability to credit insurance premiums charged periodically, rather than as a lump-sum added to the loan amount at closing. Since publication of the final rule, industry stakeholders have expressed concern that the regulation text and preamble left substantial uncertainty about whether, and under what circumstances, premiums for certain credit insurance products can be charged on a periodic basis in connection with a covered consumer credit transaction secured by a dwelling. These stakeholders have requested clarification on § 1026.36(i)'s applicability to these credit insurance products and also have expressed concern regarding their ability to comply timely, given that the Final Rule provided an effective date for § 1026.36(i) of June 1, 2013. In light of the interpretive questions that have arisen since publication of the Final Rule, the Bureau intends to publish a new proposal to seek further notice and comment on the provision in June 2013. In that proposal, among other things, the Bureau plans to (1) seek public comment, including from industry stakeholders and consumers, regarding the applicability of the prohibition to transactions in which credit insurance premiums are charged periodically; and (2) propose a new effective date for § 1026.36(i), under which the provision would take effect some time after finalization of that proposal.

In the interim, the Bureau is proposing to temporarily delay the June 1, 2013, effective date of § 1026.36(i). The Bureau is concerned that, if the effective date is not delayed, creditors could face uncertainty about whether and under what circumstances credit insurance premiums may be charged periodically in connection with covered consumer credit transactions secured by a dwelling. The Bureau believes this could result in a substantial compliance burden to industry. The Bureau thus proposes that the effective date for § 1026.36(i) be temporarily delayed. The Bureau contemplates delaying the effective date only as long as necessary for any clarifications to be proposed, finalized, and implemented. The Bureau solicits comment on what that new date should be. Further, whatever new effective date the Bureau may announce as a result of this proposal, the Bureau also intends to propose and again seek comment on the effective date for any clarifications to § 1026.36(i) as part of the forthcoming June proposal. The Bureau believes that the temporary delay would balance the need for consumers to receive the protections

[4] 15 U.S.C. 1639(d).

[5] 77 FR 55272 (Sept. 7, 2012).

afforded by the rule as quickly as possible with industry's need to make adjustments to comply with the provisions of the rule.

IV. Section 1022(b)(2) of the Dodd-Frank Act

The Bureau is considering the potential benefits, costs, and impacts of the proposed rule.[6] The Bureau requests comment on the preliminary analysis presented below as well as submissions of additional data that could inform the Bureau's analysis of the benefits, costs, and impacts of the proposed rule. The Bureau has consulted, or offered to consult with, the prudential regulators, SEC, HUD, VA, USDA, FHFA, the Federal Trade Commission, and the Department of the Treasury, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies.

In part VII of the Final Rule, the Bureau previously considered the costs, benefits, and impact of § 1026.36(i) as adopted by the Final Rule. The Bureau believes that, compared to the baseline established by the Final Rule,[7] the proposed delay of § 1026.36(i)'s effective date would generally benefit creditors and the credit insurance industry by delaying the start of ongoing compliance costs, and allowing time for a process to clarify the scope and compliance requirements of the regulation. Creditors and the credit insurance industry would benefit to the extent that the changes eliminate any disruptions in the provision of credit insurance products to consumers while interpretive questions concerning § 1026.36(i) are addressed. The Bureau believes that delaying the effective date of § 1026.36(i) would also delay the consumer benefit that would result from allowing the rule to take effect. Specifically, delaying the effective date would delay the prohibition on lump-sum credit insurance premiums added to the loan amount at closing, which Congress sought to prohibit through TILA section 129C.

In addition, the proposed rule is not expected to have a differential impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act or on consumers in rural areas. The Bureau does not believe that the proposed rule would meaningfully reduce consumers' access to consumer products and services.

V. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements.[8] These analyses must ''describe the impact of the proposed rule on small entities.''[9] An IRFA or FRFA is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities,[10] or if the agency considers a series of closely related rules as one rule for purposes of complying with the IRFA or FRFA requirements.[11] The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives prior to proposing a rule for which an IRFA is required.[12]

The Bureau concludes that an IRFA is not required for this proposed rule because the proposed rule, if adopted, would not have a significant impact on a substantial number of small entities. As discussed above, the proposal would temporarily delay the June 1, 2013 effective date of § 1026.36(i), as adopted by the Final Rule, pending the finalization of a forthcoming proposal that will address certain interpretive questions that have arisen regarding the application of the provision to non-lump sum credit insurance products. The Bureau will determine the new effective date when it finalizes that proposal. The delay in effective date will benefit small creditors by delaying the start of any ongoing compliance costs. Accordingly, the undersigned hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

VI. Paperwork Reduction Act Analysis

The Bureau may not conduct or sponsor, and, notwithstanding any other provision of law, a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. Regulation Z currently contains collections of information approved by OMB. The Bureau's OMB control number for Regulation Z is 3170–0015. However, the Bureau has determined that this proposed rule would not materially alter these collections of information or impose any new recordkeeping, reporting, or disclosure requirements on the public that would constitute collections of information requiring approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Comments on this determination may be submitted to the Bureau as instructed in the **ADDRESSES** section of this notice and to the attention of the Paperwork Reduction Act Officer.

Dated: May 7, 2013.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2013–11223 Filed 5–8–13; 11:15 am]

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[6] Section 1022(b)(2)(A) of the Dodd-Frank Act, 12 U.S.C. 5521(b)(2), directs the Bureau, when prescribing a rule under the Federal consumer financial laws, to consider the potential benefits and costs of regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on insured depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas. Section 1022(b)(2)(B) of the Dodd-Frank Act directs the Bureau to consult with appropriate prudential regulators or other Federal agencies regarding consistency with prudential, market, or systemic objectives that those agencies administer.

[7] The Bureau has discretion in any rulemaking to choose an appropriate scope of analysis with respect to potential benefits and costs and an appropriate baseline.

[8] 5 U.S.C. 601 *et seq.*

[9] 5 U.S.C. 603(a). For purposes of assessing the impacts of the proposed rule on small entities, ''small entities'' is defined in the RFA to include small businesses, small not-for-profit organizations, and small government jurisdictions. 5 U.S.C. 601(6). A ''small business'' is determined by application of Small Business Administration regulations and reference to the North American Industry Classification System (NAICS) classifications and size standards. 5 U.S.C. 601(3). A ''small organization'' is any ''not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' 5 U.S.C. 601(4). A ''small governmental jurisdiction'' is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. 5 U.S.C. 601(5).

[10] 5 U.S.C. 605(b).

[11] 5 U.S.C. 605(c).

[12] 5 U.S.C. 609.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0368; Directorate Identifier 2012–NM–058–AD]

RIN 2120–AA64

Airworthiness Directives; the Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 777–200 and –300 series airplanes. This proposed AD was prompted by reports

of smoke or flames in the passenger cabin of various transport category airplanes related to the wiring for the passenger cabin in-flight entertainment (IFE) system, cabin lighting, and passenger seats. This proposed AD would require installing wiring and changing certain electrical load management system (ELMS) panels and other concurrent requirements to ensure the flightcrew is able to turn off electrical power to the IFE systems and other non-essential electrical systems through a switch in the flight compartment in the event of smoke or flames. In the event of smoke or flames in the airplane flight deck or passenger cabin, the flightcrew's inability to turn off electrical power to the IFE system and other non-essential electrical systems could result in the inability to control smoke or flames in the airplane flight deck or passenger cabin during a non-normal or emergency situation, and consequent loss of control of the airplane.

DATES: We must receive comments on this proposed AD by June 24, 2013.

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

- *Federal eRulemaking Portal:* Go to *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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Ray Mei, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6467; fax: 425–917–6590; email: *raymont.mei@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0368; Directorate Identifier 2012–NM–058–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

In response to reports of smoke or flames in the passenger cabin of various models of transport category airplanes (The Boeing Company Model MD–11 and DC–9 airplanes and Lockheed Martin Corporation/Lockheed Martin Aeronautics Company Model L–1011 series airplanes), we conducted a comprehensive IFE systems review. Earlier investigation of the reports had revealed that the source of the smoke and flames was from cabin IFE system components, passenger seats, and cabin lighting.

We determined that, in order to minimize the risk of smoke or flames in the passenger cabin, a switch is needed in the flight compartment to enable the flightcrew to turn off electrical power to the IFE system and other non-essential electrical systems. In the event of smoke or flames in the airplane flight deck or passenger cabin, the flightcrew's inability to turn off power to the IFE system and other non-essential electrical systems, if not corrected, could result in the inability to control smoke or flames in the airplane flight deck or passenger cabin during a non-normal or emergency situation.

Other Relevant Rulemaking

- For the Boeing Company Model 757–200 and –300 series airplanes: AD 2007–16–12, Amendment 39–15151 (72 FR 44740, August 9, 2007), requires changes to existing wiring; installation of new circuit breakers, relays, relay connectors, and wiring; and replacement of certain circuit breakers with higher-rated circuit breakers. For certain airplanes, that AD also requires modification of wiring of the control module assembly for the electrical systems.
- For the Boeing Company Model 767–200, –300, and –400ER series airplanes: AD 2008–23–15, Amendment 39–15736 (73 FR 70267, November 20, 2008), requires installing new relay(s), circuit breakers (as applicable), and wiring to allow the flightcrew to turn off electrical power to the IFE systems and certain circuit breakers through a utility bus switch; and doing other specified actions.
- For the Boeing Company Model 737–300, –400, –500, –600, –700, –700C, –800, and –900 series airplanes: AD 2009–12–06, Amendment 39–15929 (74 FR 27698, June 11, 2009), requires installing a new circuit breaker, relays, and wiring to allow the flightcrew to turn off electrical power to the IFE systems and other non-essential electrical systems through a switch in the flight compartment; and doing other specified actions.
- For the Boeing Company Model 747–400 and –400D series airplanes: AD 2009–15–12, Amendment 39–15975 (74 FR 35789, July 21, 2009), requires installing new relays to allow the flightcrew to turn off electrical power to the IFE system and other non-essential passenger cabin systems through the left and right utility bus switches; and doing other specified actions.

Relevant Service Information

We reviewed Boeing Service Bulletin 777–24–0075, Revision 3, dated August 26, 2010. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for Docket No. FAA–2013–0368.

Concurrent Service Information

Boeing Service Bulletin 777–24–0075, Revision 3, dated August 26, 2010, specifies prior or concurrent accomplishment of Boeing Service Bulletins 777–23–0142, dated November 25, 2003; 777–23–0175, Revision 2,

dated October 12, 2006; 777–24–0074, Revision 4, dated September 13, 2012; and 777–24–0087, Revision 2, dated August 16, 2007. For information on the procedures, see this service information at *http://www.regulations.gov* by searching for Docket No. FAA–2013–0368.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information identified previously, except as discussed under ''Differences Between the Proposed AD and the Service Information.''

The phrase ''related investigative actions'' might be used in this proposed AD. ''Related investigative actions'' are follow-on actions that (1) are related to the primary action, and (2) are actions that further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

In addition, the phrase ''corrective actions'' might be used in this proposed AD. ''Corrective actions'' are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between the Proposed AD and the Service Information

Section 1.B, ''Concurrent Requirements,'' of Boeing Service Bulletin 777–24–0075, Revision 3, dated August 26, 2010, identifies Boeing Service Bulletin 777–24–0074, dated June 27, 2002; and Revision 1, dated October 5, 2006; as concurrent service bulletins. However, this proposed AD would require Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012, as a concurrent service bulletin.

This proposed AD gives credit for Boeing Service Bulletin 777–24–0074, dated June 27, 2002; Revision 1, dated October 5, 2006; Revision 2, dated May 20, 2010; and Revision 3, dated February 20, 2012; provided that certain concurrent requirements and additional work identified in Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012, are done.

Costs of Compliance

We estimate that this proposed AD affects 59 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installation of wiring and changing ELMS panel wiring.	36 work-hours × $85 per hour = $3,060	$2,503	$5,563	$328,217
Concurrent ELMS software installation (Boeing Service Bulletin 777-24-0087, Revision 2, dated August 16, 2007).	3 work-hours × 85 per hour = 255	0	255	15,045
Concurrent OPS change (Boeing Service Bulletin 777–23–0175, Revision 2, dated October 12, 2006).	4 work-hours × 85 per hour = 340	0	340	20,060
Concurrent power isolation switch installation (Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012).	5 work-hours × 85 per hour = 425	751	1,176	69,384
Concurrent CSS hardware and software change (No affected U.S. operators; Boeing Service Bulletin 777-23-0142, dated November 25, 2003).	10 work-hours × 85 per hour = 850	119,959	120,809	0

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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2013–0368; Directorate Identifier 2012–NM–058–AD.

(a) Comments Due Date

We must receive comments by June 24, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 777–200 and −300 series airplanes, certificated in any category, as identified in Boeing Service Bulletin 777–24–0075, Revision 3, dated August 26, 2010.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Unsafe Condition

This AD was prompted by reports of smoke or flames in the passenger cabin of various transport category airplanes related to the wiring for the passenger cabin in-flight entertainment (IFE) system, cabin lighting, and passenger seats. We are issuing this AD to ensure the flightcrew is able to turn off electrical power to the IFE systems and other non-essential electrical systems through a switch in the flight compartment in the event of smoke or flames. In the event of smoke or flames in the airplane flight deck or passenger cabin, the flightcrew's inability to turn off electrical power to the IFE system and other non-essential electrical systems could result in the inability to control smoke or flames in the airplane flight deck or passenger cabin during a non-normal or emergency situation, and consequent loss of control of the airplane.

(f) Compliance

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

(g) Installation

Within 60 months after the effective date of this AD, install certain wiring and change certain electrical load management system (ELMS) panels; as identified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 777–24–0075, Revision 3, dated August 26, 2010.

(h) Concurrent Requirements

(1) For airplanes identified in Boeing Service Bulletin 777–23–0142, dated November 25, 2003: Prior to or concurrently with accomplishing the requirements of paragraph (g) of this AD, change the hardware and software for the cabin services system, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 777–23–0142, dated November 25, 2003.

(2) For all airplanes: Prior to or concurrently with accomplishing the requirements of paragraph (g) of this AD, change the operations software (OPS) of the cabin management system, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 777–23–0175, Revision 2, dated October 12, 2006.

(3) For Group 1, Configurations 1, 3, and 4 airplanes, specified in Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012: Prior to or concurrently with accomplishing the requirements of paragraph (g) of this AD, install certain new electrical power control panels; as identified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012.

(4) For Group 1, Configuration 2 airplanes, specified in Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012: Prior to or concurrently with accomplishing the requirements of paragraph (g) of this AD, inspect the electrical power control panel for a certain part number and change the part number, as applicable; as identified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012.

(5) For all airplanes: Prior to or concurrently with accomplishing the requirements of paragraph (g) of this AD, change the ELMS OPS and configuration database software (OPC) at the data loader, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 777–24–0087, Revision 2, dated August 16, 2007.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 777–24–0075, dated August 21, 2003; or Revision 1, dated December 11, 2003; which are not incorporated by reference in this AD; provided that the Smiths Service Bulletin 5000ELM–24–379 identified on pages 8 and 19 of Boeing Service Bulletin 777–24–0075, Revision 1, dated December 11, 2003, is not used.

(2) This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 777–24–0075, Revision 2, dated October 5, 2006.

(3) This paragraph provides credit for the actions required by paragraph (h)(5) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 777–24–0087, dated July 24, 2003; or Revision 1, dated December 18, 2003.

(4) This paragraph provides credit for the actions required by paragraphs (h)(3) and (h)(4) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 777–24–0074, dated June 27, 2002; Revision 1, dated October 5, 2006; Revision 2, dated May 20, 2010; or Revision 3, dated February 20, 2012; provided all applicable concurrent requirements identified in Section 1.B of Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012, have been done prior to or concurrently with that revision; and provided that any additional work identified by the phrase ''More work is necessary'' in section 1.D of Boeing Service Bulletin 777–24–0074, Revision 4, dated September 13, 2012, is accomplished before the effective date of this AD.

(5) This paragraph provides credit for the actions required by paragraph (h)(2) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 777–23–0175, dated July 11, 2002; or Revision 1, dated July 17, 2003; provided that overhead electronics unit hardware, part number 285W0029–5, is not installed.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(k) Related Information

(1) For more information about this AD, contact Ray Mei, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6467; fax: 425–917–6590; email: *raymont.mei@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 26, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–11063 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0370; Directorate Identifier 2013–NM–034–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), CL–600–2D15 (Regional Jet Series 705), and CL–600–2D24 (Regional Jet Series 900) airplanes. This proposed AD was prompted by a report that traces of oil could be found in the crew oxygen system due to the use of incorrect pressure testing procedures during manufacturing. This proposed AD would require cleaning the crew oxygen system. We are proposing this AD to detect and correct oil contaminants, which could cause an ignition and result in a fire in the oxygen system.

DATES: We must receive comments on this proposed AD by June 24, 2013.

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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com*; Internet *http://www.bombardier.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations 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: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7318; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0370; Directorate Identifier 2013–NM–034–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Transport Canada Civil Agency, which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2013–01, dated January 22, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> It was found that traces of oil could be present in the crew oxygen system due to the use of incorrect pressure testing procedures during manufacturing. Field sampling of nine aeroplanes have confirmed this condition. When the oxygen system is used, oil contaminants can cause an ignition and result in a fire in the oxygen system.
>
> This [TCCA] AD mandates the cleaning of the crew oxygen system to reduce oil contaminants to a safe level.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Bombardier, Inc. has issued Service Bulletin 670BA–35–012, Revision A, dated November 26, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 400 products of U.S. registry. We also estimate that it would take about 51 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $827 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $2,064,800, or $5,162 per product.

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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2013–0370; Directorate Identifier 2013–NM–034–AD.

(a) Comments Due Date

We must receive comments by June 24, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial numbers 10002 through 10265 inclusive; and Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15002 through 15153 inclusive, 15156 and 15157; certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Reason

This AD was prompted by a report that traces of oil could be found in the crew oxygen system due to the use of incorrect pressure testing procedures during manufacturing. We are issuing this AD to detect and correct oil contaminants, which could cause an ignition and result in a fire in the oxygen system.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Actions

Within 6,600 flight hours or 36 months after the effective date of this AD, whichever occurs first: Clean the crew oxygen system, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–35–012, Revision A, dated November 26, 2012.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–35–012, dated August 3, 2012, which is not incorporated by reference.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(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.

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2013–01, dated January 22, 2013, and Bombardier Service Bulletin 670BA–35–012, Revision A, dated November 26, 2012, for related information.

Issued in Renton, Washington, on May 2, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–11169 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0369; Directorate Identifier 2012–NM–128–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 757 airplanes. This proposed AD was prompted by reports of fractured rudder pedal pushrod connecting bolts in a rudder pedal assembly. This proposed AD would require repetitive replacements of the rudder pedal pushrod connecting bolts and repetitive inspections of the rudder pedal assembly bolt holes in each of the captain and the first officer rudder pedal assemblies, and if necessary, repair or replacement of worn rudder pedal assemblies. We are proposing this AD to prevent fracture of the rudder pedal pushrod connecting bolts during pedal use, which could result in a large involuntary input to the rudder, nose-wheel steering, and braking systems, leading to a runway excursion.

DATES: We must receive comments on this proposed AD by June 24, 2013.

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

- *Federal eRulemaking Portal:* Go to *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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, FAA, ANM–130S, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: 425–917–6418; fax: 425–917–6590; email: *marie.hogestad@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0369; Directorate Identifier 2012–NM–128–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We received reports of fractured rudder pedal pushrod connecting bolts on Boeing Model 757 airplanes. One operator discovered a bolt was fractured during an inspection, following a report that the captain's right pedal was loose. Another operator reported a fractured bolt during the airplane pushback. When the captain applied the brakes, the right hand rudder pedal collapsed and both pedals fell forward. An inspection revealed that a rudder pedal pushrod bolt was fractured, resulting in a full left rudder input. Also, in a separate incident, during routine maintenance, while the brakes were released, a loud crack was heard and the right hand rudder pedal went all the way forward. During investigation, it was determined that the captain's right hand rudder pedal pushrod bolt had fractured. The rudder pedal pushrod connecting bolt secures the rudder pedal arm to the rudder pushrod. The bolt is cantilevered in a single shear arrangement that is not capable of carrying its design load if there is looseness in the installation (bolt bending is introduced). The bolts can also rotate, due to lack of bolt clamp-up, causing additional wear. This condition, if not corrected, could result in a fracture of the rudder pedal pushrod connecting bolts during pedal use, which could result in large involuntary input to the rudder, nose-wheel steering, and braking systems, leading to a runway excursion.

Related Rulemaking

We issued AD 2001–22–13, Amendment 39–12492 (66 FR 55075, November 1, 2001), for certain Model 737, 747, 757, 767, and 777 series airplanes. That AD requires replacing the rudder pedal pushrod fasteners (bolts) for the captain's and first officer's pedal assemblies with titanium fasteners (bolts).

We have determined that titanium bolts are under-strength on Model 757 airplanes and must be replaced with Inconel bolts. Titanum bolts do, however, meet the static and fatigue requirements for the other airplane models affected by AD 2001–22–13, Amendment 39–12492 (66 FR 55075, November 1, 2001).

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for Docket No. FAA–2013–0369.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously. Replacements of the rudder pedal pushrod connecting bolts are done after each inspection specified in paragraph (g) of this AD, regardless of the inspection results. Some actions would terminate the requirements of AD 2001–22–13, Amendment 39–12492 (66 FR 55075, November 1, 2001), for Model 757 airplanes.

Costs of Compliance

We estimate that this proposed AD affects 685 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect/replace bolts (Condition 1 in the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012).	5 work-hours × $85 per hour = $425 per inspection cycle.	$217	$642 per inspection cycle	$439,770 per inspection cycle.

We estimate the following costs to do any necessary repairs/replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these repairs/replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace rudder pedal assembly (Condition 2 in the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012).	2 work-hours × $85 per hour = $170.	Unknown	$170
Repair rudder pedal assembly (Condition 3 in the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012).	3 work-hours × $85 per hour = $255.	Unknown	255
Repair rudder pedal assembly (Condition 4 in the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012).	4 work-hours × $85 per hour = $340.	Unknown	340

The on-condition costs in the table above are per rudder pedal assembly. Depending on the diamater of the holes found during the inspection, it may be necessary to replace or repair the rudder pedal assemblies. The parts cost to replace or repair the rudder pedal assemblies are not included in the estimate. It is considered ''Parts & Materials Supplied by the Operator'', which is referenced in Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

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 proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2013–0369; Directorate Identifier 2012–NM–128–AD.

(a) Comments Due Date

We must receive comments by June 24, 2013.

(b) Affected ADs

Certain requirements of this AD terminate the requirements of AD 2001–22–13, Amendment 39–12492 (66 FR 55075, November 1, 2001), for Model 757 airplanes.

(c) Applicability

This AD applies to all The Boeing Company Model 757–200, –200PF, –200CB, and –300 series airplanes, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Unsafe Condition

This AD was prompted by reports of fractured rudder pedal pushrod connecting bolts in the rudder pedal assembly. We are issuing this AD to prevent fracture of the rudder pedal pushrod connecting bolts during pedal use, which could result in a large involuntary input to the rudder, nose-wheel steering, and braking systems, leading to a runway excursion.

(f) Compliance

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

(g) Inspection

Within 60 months after the effective date of this AD, do a detailed inspection of the rudder pedal assembly bolt holes to determine the diameter, in each of the captain and the first officer rudder pedal assemblies, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012. Repeat this inspection thereafter at intervals not to exceed 15,000 flight cycles.

(h) Installation

Do the applicable actions specified in paragraph (h)(1), (h)(2), or (h)(3) of this AD for each of the captain and first officer rudder pedal assemblies, based on the results of any inspection required by paragraph (g) of this AD. Accomplishment of paragraph (h)(1), (h)(2), or (h)(3) of this AD terminates the requirements of AD 2001–22–13, Amendment 39–12492 (66 FR 55075, November 1, 2001), for that Model 757 airplane only.

(1) If the diameters of both holes are within 0.3120 and 0.3140 inch on the assembly, before further flight, install new rudder pedal pushrod connect bolt, washer, nut, and cotter pin, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

(2) If the diameter of only one hole is greater than 0.3140 inch on the assembly, before further flight, do the actions specified in paragraphs (h)(2)(i) and (h)(2)(ii) of this AD.

(i) Install a new rudder pedal assembly, or install a bushing in the worn hole, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

(ii) Install new rudder pedal pushrod connecting bolt, washer, nut, and cotter pin, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

(3) If the diameters of both holes are greater than 0.3140 inch on the assembly, before further flight, do the actions specified in paragraphs (h)(3)(i) and (h)(3)(ii) of this AD.

(i) Install a new rudder pedal assembly, or install two bushings in the two worn holes, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

(ii) Install new rudder pedal pushrod connecting bolt, washer, nut, and cotter pin, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, as revised by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

(i) Parts Installation

As of the effective date of this AD, no person may install, in a rudder pedal assembly of any Boeing 757 airplane, a bolt having part number (P/N) BACB30NM5DK47.

(j) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraphs (g) and (h) of this AD, if operators installed washers having part number NAS1149D0516J, NAS1149D0532J, and NAS1149D0563J, and if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 757–27A0153, dated May 9, 2012, which is not incorporated by reference in this AD, as unmodified by Boeing Alert Service Bulletin 757–27A0153, Revision 1, dated October 29, 2012.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(l) Related Information

(1) For more information about this AD, contact Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, FAA, ANM–130S, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: 425–917–6418; fax: 425–917–6590; email: *marie.hogestad@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on May 2, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–11168 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0367; Directorate Identifier 2012–NM–177–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, and Model CL–600–2D24 (Regional Jet Series 900) airplanes. This proposed AD was prompted by a report of corrosion of the components of the main landing gear (MLG) retraction actuator found in service; the corrosion was found at the interface of the rod end and the piston, and at the bracket and related pins. This proposed AD would require inspection of the MLG retraction actuator components; corrective actions if necessary; and, for certain retraction actuators, installation of a new jam nut. We are proposing this AD to prevent disconnection of the MLG retraction actuator, which could result in extension of the MLG without damping,

and consequent structural damage and collapse of the MLG during landing.

DATES: We must receive comments on this proposed AD by June 24, 2013.

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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For Bombardier service information identified in this proposed AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com*; Internet *http://www.bombardier.com*. For Goodrich service information identified in this proposed AD, contact Goodrich Corporation, Landing Gear, 1400 South Service Road, West Oakville L6L 5Y7, Ontario, Canada; telephone 905–825–1568; email *jean.breed@goodrich.com*; Internet *http://www.goodrich.com/TechPubs*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations 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: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7318; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0367; Directorate Identifier 2012–NM–177–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2011–36R1, dated October 3, 2012 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Corrosion of the main landing gear (MLG) retraction actuator components was found in-service, either at the interface of the rod end and the piston or at the bracket and its related pins. This can cause the MLG retraction actuator to disconnect, leading to an MLG extension without damping, and a potential for MLG structural damage and possible collapse during landing.
>
> This [Canadian] AD mandates the inspection and rectification [corrective action] of the MLG retraction actuator components.
>
> This revision is to mandate [, for certain MLG retraction actuators,] the installation of the new retraction actuator jam nut. This revision also corrects the background information and updates Service Bulletin (SB) references.

The required inspection includes, for certain MLG retraction actuator assemblies, a detailed inspection of the retraction actuator assembly for evidence of corrosion, and security of the jam nut; and, for certain MLG dressed shock struts, a detailed inspection for evidence of corrosion of the retract actuator bracket assembly, associated pins, and mating lugs on the outer cylinder and a detailed inspection of the associated pins for chrome damage. The corrective actions include replacing pins that have chrome damage or evidence of corrosion, replacing retraction actuator bracket assemblies and mating lugs that have evidence of corrosion. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Bombardier, Inc. has issued the following service bulletins.

- Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012.
- Bombardier Service Bulletin 670BA–32–033, Revision B, dated Jun 26, 2012.

Goodrich Corporation has issued the following service bulletins.

- Goodrich Service Bulletin 49000–32–46, Revision 2, dated November 11, 2011.
- Goodrich Service Bulletin 49600–32–63, Revision 1, dated May 17, 2011.
- Goodrich Service Bulletin 49600–32–64, Revision 3, dated December 15, 2011.

The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

The MCAI specifies using ''later approved revisions'' of the service information when accomplishing the requirements. However, ''later approved revisions'' must not be used in an AD when referring to the service document because doing so violates Office of the Federal Register (OFR) regulations for approval of materials ''incorporated by reference'' in rules. Therefore, we have not included ''later approved revisions'' in this proposed AD. If additional parts are identified in later revisions of the service information, we might consider further rulemaking then.

Goodrich Service Bulletin 49600–32–63, Revision 1, dated May 17, 2011, specifies to return retract actuators to Goodrich if corrosion is found or if a jam nut is not secured. However, this proposed AD would require replacing the retract actuators with new or

serviceable retract actuators if those conditions are found.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 391 products of U.S. registry. We also estimate that it would take up to 16 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $1,018 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be up to $929,798, or up to $2,378 per product.

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

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

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

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2013–0367; Directorate Identifier 2012–NM–177–AD.

(a) Comments Due Date

We must receive comments by June 24, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes specified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial numbers 10002 and subsequent.

(2) Bombardier, Inc. Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 and subsequent.

(d) Subject

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

(e) Reason

This AD was prompted by a report of corrosion of the components of the main landing gear (MLG) retraction actuator found in service; the corrosion was found at the interface of the rod end and the piston, and at the bracket and related pins. We are issuing this AD to prevent disconnection of the MLG retraction actuator, which could result in extension of the MLG without damping, and consequent structural damage and collapse of the MLG during landing.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Inspection of the MLG Retraction Actuator and Corrective Actions

For any airplane with a MLG retraction actuator assembly having any part number and serial number identified in paragraph 1.A., Effectivity, of Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012, except airplanes on which modification status ''32–64'' is marked on the identification plate: At the applicable time specified in paragraph (g)(1) or (g)(2) of this AD, perform a detailed inspection of the retraction actuator assembly for evidence of corrosion and security of the jam nut, as applicable, in accordance with Part A of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012; and Goodrich Service Bulletin 49600–32–63, Revision 1, dated May 17, 2011. If any corrosion or unsecured jam nut is found, before further flight, replace the retract actuator with a new or serviceable retract actuator; install the retract actuator in accordance with Part A of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012. Repeat the inspection at intervals not to exceed 1,200 flight hours or 12 months, whichever occurs first.

(1) For MLG retraction actuator assemblies on which, as of the effective date of this AD, 8,000 or more total flight hours have accumulated since new or since overhaul, or have been in service for more than 4 years since new or since overhaul: Inspect within 1,200 flight hours or 12 months after the effective date of this AD, whichever occurs first.

(2) For MLG retraction actuator assemblies on which, as of the effective date of this AD, less than 8,000 total flight hours have accumulated since new or since overhaul, and have been in service for 4 years or less since new or since overhaul: Inspect before the accumulation of 9,200 total flight hours on the MLG retraction actuator assembly since new or since overhaul or within 5 years in service since new or since overhaul, whichever occurs first.

(h) Inspection of MLG Retraction Actuator Bracket and Related Pins, and Corrective Actions

For any airplane with a MLG dressed shock strut having any part number and serial number identified in paragraph 1.A., Effectivity, of Bombardier Service Bulletin 670BA–32–033, Revision B, dated June 26, 2012: Within 4,400 flight hours or 24 months after the effective date of this AD, whichever occurs first, perform a detailed inspection of the retract actuator bracket assembly, associated pins, and the mating lugs on the outer cylinder for evidence of corrosion, in accordance with Bombardier Service Bulletin

670BA–32–033, Revision B, dated June 26, 2012; and Goodrich Service Bulletin 49000–32–46, Revision 2, dated November 11, 2011. Do all applicable corrective actions before further flight (i.e., replace retract actuator bracket assembly and pins, or outer cylinder lugs, as applicable).

(i) Installation of New Jam Nut

For any airplane with a MLG retraction actuator assembly having any part number and serial number identified in paragraph 1.A., Effectivity, of Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012, except airplanes on which modification status ''32–64'' is marked on the identification plate: Within 20,000 flight hours or 10 years after the effective date of this AD, whichever occurs first, install a new jam nut having part number 49606–5, in accordance with Part B of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012; and Goodrich Service Bulletin 49600–32–64, Revision 3, dated December 15, 2011.

(j) Credit for Previous Actions

(1) This paragraph provides credit for the actions required by paragraphs (g) and (i) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–32–031, dated March 14, 2011; Revision A, dated June 9, 2011; or Revision B, dated July 29, 2011; which are not incorporated by reference in this AD.

(2) This paragraph provides credit for the actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–32–033, dated March 14, 2011; or Revision A, dated July 29, 2011; which are not incorporated by reference in this AD.

(k) Parts Installation Limitations

(1) As of the effective date of this AD, no person may install on any airplane a MLG retraction actuator assembly having any part number and serial number identified in paragraph 1.A., Effectivity, of Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012, unless that retraction actuator assembly has been inspected as specified in paragraph (g) of this AD, and all applicable corrective actions (i.e., replacement of the retract actuator) specified in paragraph (g) of this AD have been done. Repeat the inspection specified in paragraph (g) of this AD thereafter at the intervals specified in paragraph (g) of this AD.

(2) As of the effective date of this AD, no person may install on any airplane a MLG retraction actuator assembly having any part number and serial number identified in paragraph 1.A., Effectivity, of Bombardier Service Bulletin 670BA–32–033, Revision B, dated June 26, 2012, unless that retraction actuator assembly has been inspected and all applicable corrective actions have been done, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–32–033, Revision B, dated June 26, 2012.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(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.

(m) Related Information

(1) Refer to mandatory continued airworthiness information (MCAI) Canadian Airworthiness Directive CF–2011–36R1, dated October 3, 2012, and the service bulletins specified in paragraphs (m)(1)(i) through (m)(1)(v) of this AD, for related information.

(i) Bombardier Service Bulletin 670BA–32–031, Revision C, dated April 17, 2012.

(ii) Bombardier Service Bulletin 670BA–32–033, Revision B, dated June 26, 2012.

(iii) Goodrich Service Bulletin 49000–32–46, Revision 2, dated November 11, 2011.

(iv) Goodrich Service Bulletin 49600–32–63, Revision 1, dated May 17, 2011.

(v) Goodrich Service Bulletin 49600–32–64, Revision 3, dated December 15, 2011.

(2) For Bombardier service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com*; Internet *http://www.bombardier.com*. For Goodrich service information identified in this AD, contact Goodrich Corporation, Landing Gear, 1400 South Service Road, West Oakville L6L 5Y7, Ontario, Canada; telephone 905–825–1568; email *jean.breed@goodrich.com*; Internet *http://www.goodrich.com/TechPubs*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 26, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–11067 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 5

[Docket No. USCG–1999–6712]

RIN 1625–AB66

Revision of Auxiliary Regulations

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise and reorganize the regulations that govern the operation and administration of the Coast Guard Auxiliary, a uniformed, volunteer, non-military organization chartered by Congress. The proposed changes would conform the regulatory language to changes in the laws governing the Coast Guard Auxiliary, clarify the Auxiliary's organization, status, and role in Coast Guard operations, and update provisions on liability protection for Auxiliary members assigned to Coast Guard duty.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before August 8, 2013 or reach the Docket Management facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–1999–6712 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section

below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Mr. Stephen Minutolo, CG–BSX–11, U.S. Coast Guard Headquarters, 2100 2nd St. SW., Stop 7581, Washington, DC 20593–7581; telephone 202 372–1267; email *hqs-dg-m-cgauxregs@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–1999–6712), 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. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that the Coast Guard can contact you if the Coast Guard has questions regarding your submission.

To submit your comments online, go to *http://www.regulations.gov.* Insert ''USCG–1999–6712'' in the Search box and click ''Search.'' Click on the ''Comment Now'' button next on the line with this document.

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 them 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. The Coast Guard may change this proposed rule in view of your comments.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* insert ''USCG–1999–6712'' in the Search box and click ''Search.'' Click on the ''Open Docket Folder'' link and click on each comment or document you would like to view. If you do not have access to the Internet, you may view the docket by visiting 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

C. Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

D. Public Meeting

We do not now plan to hold a public meeting, but you may submit a request for one to the docket using one of the methods specified under **ADDRESSES**. In your request, explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

II. Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
Pub. L. Public Law
§ Section symbol
SAMA Standard Auxiliary Maintenance Allowance
U.S.C. United States Code
USCG United States Coast Guard
1996 Act The Coast Guard Authorization Act of 1996

III. Background

This proposed rule would revise and reorganize the regulations governing the Coast Guard Auxiliary. The Coast Guard Auxiliary regulations were last updated in 2003 (68 FR 9534, Feb 28, 2003) and 1996 (61 FR 33662, June 28, 1996), but these changes did not address all of the legislative changes being addressed in this proposed rule. Through this proposed rule, the Coast Guard would update the regulations in accordance with recent legislation; clarify Auxiliary powers, duties, and organization; amend provisions regarding Auxiliary membership; and address other administrative matters. These changes would address several problems common to Auxiliary units.

First, this proposed rule is necessary to conform Coast Guard regulations to current law. The following changes to the Auxiliary's governing statutes, codified at Title 14, Chapter 23 of the U.S. Code (collectively referred to in this document as ''legislative changes'') are addressed by this rulemaking:

- The Coast Guard and Maritime Transportation Act of 2012 (Pub. L. 112–213) section 215, extending eligibility for Auxiliary membership to nationals of the United States and aliens lawfully admitted for permanent residence.
- The Coast Guard and Maritime Transportation Act of 2006 (Pub. L. 109–241) section 208, authorizing the Auxiliary to use motor vehicles in support of Auxiliary functions and duties.
- The Coast Guard and Maritime Transportation Act of 2004 (Pub. L. 108–293), section 226, allowing personal property of the Auxiliary to be treated as United States property for liability purposes.
- The Maritime Transportation Security Act of 2002 (Pub. L. 107–295), section 415, authorizing payment of a death gratuity to Auxiliary members who died in the line of duty.
- The Coast Guard Authorization Act of 1996 (Pub. L. 104–324) (''The 1996 Act'') authorizing the Auxiliary organizational structure, extending civil liability protection to Auxiliary units and members, and authorizing the Auxiliary to form a corporation. The 1996 Act also redefined the purpose of

the Auxiliary, ''to assist the Coast Guard . . . in performing any Coast Guard function. . . . '' The previous definition enumerated specific missions (promoting safety, effecting rescues, promoting efficiency in the operation of motorboats and yachts, and fostering wider knowledge of boating laws), along with a catch-all provision (''facilitate other operations of the Coast Guard.'').

- The Coast Guard Authorization Act of 1986 (Pub L. 99–640) authorized the payment of interest on reimbursement claims.
- In 2006, conforming amendments to 14 U.S.C. 821(b) and 823a(b) in The Act to Complete the Codification of Title 46, United States Code, ''Shipping,'' as Positive Law (Pub. L. 109–304) made non-substantive, editorial changes to 14 U.S.C. 821(b) and 823a(b).

Second, this proposed rule would clarify the organization of the Auxiliary and the authority given to Auxiliary units and officers to conduct Auxiliary business. This change is necessary to help Auxiliary units interact with commercial service providers, such as banks and insurance companies, who may be reluctant to enter into a business relationship with an Auxiliary unit without a better understanding of the nature of the Auxiliary and its relationship with the regular Coast Guard.

Third, the proposed rule would clarify for operational commanders the Auxiliary's ability to participate in Coast Guard operations and to work with other federal, state and local agencies.

Finally, this proposed rule would reorganize the Auxiliary regulations by eliminating unnecessary sections and organizing 33 CFR part 5 into five subject-oriented subparts, making it easier to find regulations about particular topics.

Consistent with these objectives, the Coast Guard proposes to revise and reorganize the regulations at 33 CFR part 5.

IV. Discussion of Proposed Rule

This discussion provides both a summary and a section-by-section analysis of proposed changes to regulations in 33 CFR part 5. Generally, existing sections are removed entirely, revised, or moved to another section (where they may be revised or combined with other provisions). Added sections are entirely new numbers and headings; these sections do not exist in the current 33 CFR part 5. Removed sections exist in the current 33 CFR part 5 but not in the proposed rule. Provisions that are merely restatements of existing law will be removed from the regulations. Revised sections exist in the current 33 CFR part 5, but are being changed in the proposed rule. Often some or all of the contents of the section are exported to another section; these are identified as moved.

Tables 1A and 1B describe the proposed distribution and deletion of existing sections and the derivation of proposed new sections.

Table 1A is a distribution table. Table 1A describes what will happen to each section of the current regulations under the proposed rule. For example, the third row of Table 1A tells the reader that, in the proposed rule, § 5.05 will be moved to § 5.3(a) and how the text will change.

Table 1B is a derivation table. Table 1B describes where the provisions of the proposed regulations came from. For example, the sixth row of Table 1B tells the reader the language of § 5.10 came from §§ 5.09, 5.13 and 5.15. If, for any section there is no text in the second column, that means the proposed text is new and unrelated to the contents of the existing section. To see where the content of the existing section moved, see Table 1A.

TABLE 1A—DISTRIBUTION TABLE

Existing (old) section	Proposed (new) section	Summary of proposed changes to existing section
§ 5.01	§ 5.1	Added definitions for ''Auxiliary Act'', ''Direct law enforcement'', ''Personal property of the Auxiliary''. Amended the definitions for ''Facility or facilities'', ''Radio station'', and ''Secretary''.
§ 5.03	Revised.	
§ 5.05	Moved to § 5.3(a)	Added ''uniformed.''
§ 5.07	§ 5.7	Revised. Added new provisions.
§ 5.09	Moved to § 5.10	Revised. Eliminated minimum age requirement and 25 percent ownership requirement. Added eligibility for U.S. nationals and aliens lawfully admitted for permanent residence.
§ 5.11	Removed.	
§ 5.13	Removed.	
§ 5.15	Moved to § 5.10(b)	Revised.
§ 5.17	Moved to § 5.19.	
§ 5.19	Moved to § 5.26(b)	Revised.
§ 5.21	Moved to § 5.12.	
§ 5.23	Moved to § 5.13.	
§ 5.25	Moved to § 5.11.	
§ 5.27	Moved to § 5.22	Revised.
§ 5.29	Removed.	
§ 5.31	Moved to § 5.20(a)	Revised.
§ 5.33	Moved to § 5.26(a).	
§ 5.35	Moved to § 5.36	Revised.
§ 5.37	Moved to § 5.36	Revised.
§ 5.39	Moved to § 5.36(b).	
§ 5.41	Moved to §§ 5.32(c), 5.34(c) and 5.36(c).	Revised.
§ 5.43	Moved to § 5.30(b)(3)	Revised.
§ 5.45	Moved to § 5.36(a).	
§ 5.47(a)	Moved to § 5.42(b).	
§ 5.47(b)	Moved to § 5.42(a).	
§ 5.47(c)	Moved to § 5.41(a).	
§ 5.48(a)	Moved to § 5.40(c)(2).	
§ 5.48(b)	Moved to § 5.46(a).	
§ 5.49	Moved to § 5.30(c)(1)	Revised.

TABLE 1A—DISTRIBUTION TABLE—Continued

Existing (old) section	Proposed (new) section	Summary of proposed changes to existing section
§ 5.55	Moved to § 5.16(a).	
§ 5.57	Moved to § 5.16(b).	
§ 5.59	Moved to § 5.18(b) and (c)	Revised.
§ 5.61	Moved to § 5.14.	
§ 5.63	Moved to § 5.14.	
§ 5.65	Removed.	
§ 5.69	Removed.	

TABLE 1B—DERIVATION TABLE

Proposed (new) section	Existing (old) section	Proposed change
§ 5.1	§ 5.01	Added definitions for ''Auxiliary Act'', ''Direct law enforcement'', ''Personal property of the Auxiliary''. Amended the definitions for ''Facility or facilities'', ''Radio station'' and ''Secretary''.
§ 5.3	Paragraph (a) imported from § 5.05	Added new provisions.
§ 5.5	§ 5.05	Added new provisions.
§ 5.7	§ 5.07	Added new provisions.
§ 5.9		Added new provisions.
§ 5.10	Imported language from §§ 5.09, 5.13, and 5.15.	New section.
§ 5.11	Imported language from § 5.25.	
§ 5.12	Imported language from § 5.21	New section.
§ 5.13	Imported language from § 5.23.	
§ 5.14	Imported language from §§ 5.61 and 5.63.	New section.
§ 5.15		Reserved for future use.
§ 5.16	Imported language from §§ 5.55 and 5.57.	New section.
§ 5.17		Added new provisions.
§ 5.18	Paragraphs (b) and (c) imported language from § 5.59.	New section. Added new provisions.
§ 5.19	Imported language from § 5.17.	
§ 5.20	Imported and amended language from § 5.31.	New section.
§ 5.22	Imported language from §§ 5.27 and 5.29.	New section.
§ 5.24		New section. Added new provisions.
§ 5.26	Paragraph (a) imported from § 5.33. Paragraph (b) imported from § 5.19.	New section.
§ 5.30	Imported language from § 5.43	New section.
§ 5.32	Imported and amended language from § 5.41.	New section.
§ 5.34	Imported language from § 5.41	New section.
§ 5.36	Imported and amended provisions from §§ 5.35, 5.37, 5.39, 5.41, and 5.45.	New section.
§ 5.40	Paragraph (c)(2) imported from §§ 5.47 and 5.48.	New section. Added new provisions.
§ 5.41		Added new provisions.
§ 5.42	Imported language from 5.47(a) and (b)	New section.
§ 5.43		Added new provisions.
§ 5.44		New section. New provisions.
§ 5.45		Added new provisions.
§ 5.46	Imported language from § 5.48	New section.
§ 5.47		Added new provisions.
§ 5.48		Added new provisions.

Subpart A—General

§ 5.1—Definitions: We propose to revise this section to update several definitions.

The definition of ''Act,'' which currently includes only ''the Coast Guard Auxiliary and Reserve Act of 1941, as amended and recodified by [the] Act of August 4, 1949'' would be deleted and replaced by a new definition, ''Auxiliary Act'', which includes the provisions of the U.S. Code dealing most directly with the Auxiliary (14 U.S.C. 821–894), including the legislative changes set out in section III, Background.

The definition of ''facility'' would be amended to add motorized vehicles, trailers, and other equipment accepted for use by the Coast Guard.

The definition of ''radio station'' would be amended to clarify that it includes any equipment used for radio communications or direction finding as well as a building or vehicle housing such equipment.

The definition of ''Secretary'' would be amended to reflect the nature of the

Coast Guard's service. Most of the time, the Coast Guard is a part of the Department of Homeland Security and the Coast Guard's Secretary is the Secretary of DHS. In time of war, the Coast Guard may be transferred to the Department of the Navy, and the Coast Guard's Secretary is the Secretary of the Navy. The proposed language is standard language for Coast Guard regulations in which the term Secretary is defined.

The proposed definitions section would also include a definition of ''direct law enforcement.'' Direct law enforcement is described in Chapter 4.E. of the Auxiliary Operations Policy Manual, COMDTINST 16798.3E (series), and is used in other Auxiliary publications and section 5.20(b) of the proposed rule.

Finally, we propose to define a new term, ''Personal property of the Auxiliary,'' to cover motor boats, yachts, aircraft, radio stations, motorized vehicles, trailers, or other equipment owned by or under the administrative jurisdiction of the Auxiliary and used solely for Auxiliary purposes, as provided by section 226 of the Coast Guard and Maritime Transportation Act of 2004 (Pub. L. 108–293, codified at 14 U.S.C. 821(d)(2)).

§ 5.3—Purpose: We propose to clarify the purpose of the Auxiliary to conform to current statutory language. The new language is broader than the existing regulation, in keeping with the current language of 14 U.S.C. 822.

Proposed paragraphs (a) and (b) of this section review basic information about the Auxiliary. Paragraph (c) of this section would specify that Auxiliary units may act as caretakers, docents, or tour guides for Coast Guard and other Federal- or State-owned property, a customary role which many Coast Guard units may not be aware is an authorized mission of the Auxiliary. Paragraph (d) of this section would be a new provision supporting the Commandant's commitment to strengthening partnerships with other Federal, State and local agencies.

§ 5.5—Organization, officers, and leadership: We propose to revise this section to explain the organization and composition of the Auxiliary. Because of the Auxiliary's unique nature as a Congressionally-chartered volunteer organization, its units are sometimes not recognized as distinct from the Coast Guard. This explanation would also assist Auxiliary units in their dealings with commercial institutions (e.g. banks and insurance companies).

§ 5.7—Administration, specific authorizations: This section would address the Commandant's ability to delegate authority, and provide examples of specific actions that the Commandant has delegated to the Auxiliary. It would also clarify that the Auxiliary national board and Auxiliary districts or regions may incorporate under State law and pursuant to Coast Guard policy, and establish basic functions of the Auxiliary's national corporation.

§ 5.9—References: We propose to move the contents of existing § 5.09 to new § 5.10. We propose to add a new section § 5.9 to establish various Coast Guard directives and publications as appropriate references for the Coast Guard and the public. Those directives and publications can be found online at *http://www.uscg.mil/auxiliary/publications/comdtinst/*.

Subpart B—Membership

This proposed new subpart would contain regulations relating to members and membership eligibility, discipline and compensation.

§ 5.10—Eligibility for membership: We propose to add this section to consolidate and revise existing §§ 5.09, 5.11, 5.13, and 5.15.

Paragraph (a) would identify the basic eligibility criteria for Auxiliary membership and eliminate the minimum age requirement and the 25-percent ownership requirement in § 5.09 of the current regulations. This paragraph also incorporates the 2012 legislative change that authorizes eligibility for Auxiliary membership to include nationals of the United States [1] and aliens lawfully admitted for permanent residence. The minimum age is not set by statute.

Current Auxiliary policy does not require any portion of ownership in any vessel or other equipment as a pre-condition for membership. The 25-percent ownership requirement in the current regulations was founded on an ownership requirement in the Act of Aug 4, 1949 (63 Stat. 555) which required that members either have an ownership interest in a motorboat, yacht, aircraft, or radio station, or possess special training or experience which qualifies them for duty. Current Auxiliary policy and practice is to consider all prospective members under the ''special training or experience'' provision, including applicants who are willing to undergo training in order to qualify. Although owners of vessels or other equipment would still be eligible for membership, removing the ownership requirement from the CFR will emphasize the importance of training and experience for prospective auxiliary members and reduce the chance of a prospective member mistakenly believing that not being a vessel owner precludes him or her from membership.

Paragraph (b) incorporates the provisions of the current § 5.15—Admission for membership, without substantive change.

§ 5.11—Honorary members: Provisions of the existing § 5.11, ''Membership in military organizations'', would be removed, as they are unnecessarily duplicative of law (14 U.S.C. 825) and policy. We propose to revise this section to incorporate existing § 5.25 ''Honorary members.''

§ 5.12—Ranks, titles, designations, or grades: This new section contains language, without substantive change, from existing § 5.21.

§ 5.13—Advancement: Provisions of existing § 5.13 would be moved to § 5.10. Proposed § 5.13 states that the Commandant will prescribe policy on advancement, which will be described in Auxiliary policy manuals. This language was moved with minor edits from § 5.23.

§ 5.14—Uniforms and insignia: We propose to add this section to incorporate provisions of existing §§ 5.61 and 5.63.

§ 5.15: We propose to remove and reserve this section. The provisions of existing § 5.15 would be consolidated in § 5.10.

§ 5.16—Compensation and travel expenses: This section would specify that Auxiliarists are not authorized to receive compensation for their services, but may be paid actual necessary travel expenses. This section combines existing §§ 5.55 and 5.57.

§ 5.17—Status of members as Federal employees: Provisions of existing § 5.17 would be moved to § 5.19. We propose to add new language in this section to clarify that Auxiliarists are not considered Federal employees, except as provided by 14 U.S.C. 823a.

§ 5.18—Injury or death in the line of duty: We propose to add this section to clarify the compensation an Auxiliarist is entitled to receive if injured or killed in the performance of duty; codify Coast Guard policy on what is ''performance of duty'' in the context of Auxiliary activity, describe Auxiliarists' access to medical and dental care; and summarize compensation provisions for the beneficiaries of Auxiliarists who are injured or die in the performance of duty.

[1] ''Nationals of the United States'' includes all U.S. citizens as well as individuals who, though not citizens, owe permanent allegiance to the United States. 8 U.S.C. 1101(a) (22). Non-citizen nationals currently are primarily American Samoans and Swain Islanders.

Paragraph (a) of this section would codify Coast Guard policy and practice relating to the definition of ''performance of duty'' in the context of Auxiliary activity. The Coast Guard compensates members for injuries sustained in the performance of duty under 14 U.S.C. 707 and 832 and the Federal Employees Compensation Act, 5 U.S.C. 8101 *et seq.* Existing Coast Guard policy extends this coverage to include travel to and from the Auxiliarists' permanent residence to a place of duty (see paragraph 7.O.2.c. of the Administrative Investigation Manual COMDTINST M5830.1). This proposed rule would codify the Coast Guard's practice of including stops *en route* and incidental to duty, and travel between duty locations, as ''performance of duty.''

Paragraphs (b) and (c) of this section would specify Auxiliarists' entitlement to hospitalization, medical care, and compensation for injury or death in the performance of duty. Paragraphs (b) and (c) of this section were imported from existing § 5.59. These entitlements are taken from three different statutory provisions:

- 14 U.S.C. 832 provides that Auxiliarists are entitled to hospitalization and medical care as if they were members of the Temporary Reserve.
- 14 U.S.C. 707 provides that temporary members of the reserve who are injured or die while performing active duty will be compensated as if they were civilian employees with basic pay equivalent to grade GS–9.
- The note to 5 U.S.C. 8133 provides additional compensation eligibility for civilian employees killed in the performance of duty.

§ 5.19—Disenrollment: The provisions of existing § 5.19 would be incorporated into new § 5.28. We propose to revise this section to incorporate provisions from existing § 5.17 without substantive change.

Subpart C—Activities, Operations and Training

§ 5.20—Authority: We propose to add this section to clarify the limits on Auxiliarists' authority in the performance of their duties. Paragraph (a) would incorporate the provisions of existing § 5.31. Paragraph (b) would state the prohibition on Auxiliarists engaging in direct law enforcement or military operations. Paragraph (c) would clarify that Auxiliarists' authority in supporting enforcement of limited access areas, regulated navigation areas, and special local regulations is limited to advising the public of such restrictions.

§ 5.21: We propose to move this section to § 5.12.

§ 5.22—Assignment to duties: We propose to consolidate the provisions of existing §§ 5.27 and 5.29 regarding assignment to duty in this section.

§ 5.23: We propose to remove this section, as its provisions would be consolidated in new § 5.13.

§ 5.24—Procedure for assignment to duty: We propose to add this section to include information about procedures for assignment to duty of Auxiliarists and their facilities.

§ 5.25: We propose to remove this section, as its provisions would be consolidated in new § 5.11.

§ 5.27: We propose to remove this section, as its provisions would be consolidated in new § 5.22.

§ 5.26—Training, examination, and assignment: We propose to consolidate existing §§ 5.19 and 5.33 into this new section to explain that the Commandant will set the training, qualification and examination requirements for Auxiliarists and may authorize Auxiliarists to take correspondence and distance-learning courses from Coast Guard providers.

§ 5.29: We propose to consolidate this section into new § 5.22.

Subpart D—Facilities and Equipment

Subpart D would contain the regulations dealing with vessels, aircraft, radio stations, motor vehicles, or other equipment used by the Auxiliary, the treatment of such facilities as United States property, and the procedures for transferring administrative jurisdiction of such property to and from the Auxiliary.

§ 5.30—Facilities and other equipment: We propose to add this section to codify Coast Guard policy regarding duty status, liability protection, and status as a public vessel of facilities and other equipment used by the Auxiliary, and to revise provisions for reimbursement of facility operating expenses.

Paragraph (b)(1) ''Duty status'' would clarify that personal property of the Auxiliary (typically unit-owned property) is considered assigned to authorized Coast Guard duty at all times. This is consistent with Coast Guard policy, established by paragraph D.2. of ALCOAST 600/05, ''Changes to Auxiliary Administrative Policies.''

Paragraph (b)(2) would clarify the scope of liability protection for personal property of the Auxiliary. The Commandant has directed that personal property of the Auxiliary be treated as property of the United States for the purposes of the Federal Tort Claims Act, the Military Claims Act, the Public Vessels Act, the Suits in Admiralty Act, the Admiralty Extension Act, and other matters related to non-contractual civil liability, in accordance with provisions of 14 U.S.C. 821(d)(2), as amended by the Coast Guard and Maritime Transportation Act of 2004 (Pub L. 108–293).

Paragraph (b)(3), ''Public vessels,'' will clarify that facilities loaned or given to the Auxiliary by the Coast Guard or other Federal agencies retain their public status.

Paragraph (c), ''Expenses,'' codifies Coast Guard policy for reimbursement of expenses incurred by Auxiliarists for the use, operation, maintenance, damage, or loss of their facilities.

§ 5.31: We propose to consolidate this section into new § 5.20.

§ 5.32—Offer of member-owned vessels, aircraft, radio stations, motorized vehicles, trailers, and other equipment for use as a facility: We propose to add this section to update the terms of existing § 5.37. This proposed section would apply when Auxiliary members want to offer member-owned vessels, aircraft, radio stations, motorized vehicles, trailers, and other equipment for use as a facility. Specific procedures for these offers are in the Auxiliary Policy Manual.

§ 5.34—Offers of personal property of the Auxiliary as a facility: We propose to add this section to describe Coast Guard policy for personal property of the Auxiliary to be accepted as a facility. This proposed section would apply when an Auxiliary unit has ownership or administrative jurisdiction over a vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment and wants to offer it for use as a facility. Specific procedures for these offers are in the Auxiliary Policy Manual.

§ 5.37 Offer of facilities: We propose to remove this section as its provisions would be consolidated in new § 5.32.

§ 5.35: We propose to remove this section because it restates language contained in 14 U.S.C. 826.

§ 5.36—Loan of vessels, aircraft, radio stations, motorized vehicles, trailers, or other equipment to the Coast Guard: This section would apply when a person wants to loan a vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment to the Coast Guard for Coast Guard use. This section would consolidate and update provisions of existing §§ 5.35, 5.37, 5.39, 5.41, and 5.45 and would add motorized vehicles, trailers, and other equipment owned by members or Auxiliary units to the list of property which may be loaned to the Coast Guard. In addition, this section

would specify procedures for the return of facilities at the expiration of the loan period, clarify that facilities will not be considered loaned until accepted by a person authorized by the Commandant, and provide for waiver of loan procedures in an emergency.

§ 5.39—Acceptance of facilities: We propose to remove this section. Provisions of the existing § 5.39 would be consolidated in new § 5.30.

Subpart E—Auxiliary Markings

This new subpart will describe the distinctive marks, decals and ensigns (flags) the public is likely to see on Auxiliary facilities. Sections of the current 33 CFR part 5 will be moved into this subpart. The proposed regulations would not change the design or display of any marks, decals, or ensigns. Marks which were previously described only in the Auxiliary Manual COMDTINST M16790.1 (series) or the Coast Guard Heraldry Manual COMDTINST M5200.18A would be described here, which would help the public more easily identify Auxiliary facilities.

Auxiliary markings distinguish Auxiliary boats, aircraft, and other equipment. Ensigns are flags flown by or at an asset (e.g., flown on a flag staff at a building) to signify that the asset is associated with the Auxiliary or Coast Guard. Decals are markings adhesively applied to the asset to denote its status as an Auxiliary facility that has been accepted for use by the Coast Guard. Patrol signs are placards, normally removable and of a proportionate size for the vessel on which they are displayed, which indicate to nearby vessels that the vessel is engaged in Auxiliary activities. The Auxiliary mark is a permanent marking signifying that the asset belongs to the Auxiliary in terms of custody, ownership, or as personal property.

§ 5.40—Distinctive markings for vessels, aircraft, motorized vehicles, trailers, radio stations, and other equipment: This section incorporates provisions of the current §§ 5.47 and 5.48. We propose to add this section on facility markings to clarify for both Auxiliarists and the public the identification of Auxiliary vessels, aircraft, motorized vehicles, trailers, radio stations, and other equipment, and advise the public of the penalties for unauthorized display of Auxiliary markings.

§ 5.41—Auxiliary emblem: We propose to revise this section. Provisions of the existing § 5.41 would be distributed to §§ 5.32(c), 5.34(c), and 5.36(c). The proposed section would incorporate provisions of existing § 5.47(c) describing the Auxiliary emblem and explain the use of the emblem as identification.

§ 5.42—Auxiliary ensign: The provisions of this proposed new section would be imported from existing § 5.47 and would describe the Auxiliary ensign and its display.

§ 5.43—Auxiliary mark: We propose to revise this section. Provisions of the existing § 5.43 would be moved to § 5.30(b)(3) or removed. The proposed revised section would describe the Auxiliary mark and its display.

§ 5.44—Auxiliary facility decal: We propose to add this section to describe the Auxiliary facility decal and its display.

§ 5.45—Patrol signs: We propose to revise this section. The provisions of the current section would move to § 5.36(a). The revised section would describe the Auxiliary patrol sign and its display.

§ 5.46—Auxiliary patrol boat ensign: This proposed new section would describe the Auxiliary patrol boat ensign and its display. These provisions would be imported from the current § 5.48.

§ 5.47—Coast Guard ensign: We propose to revise this section. Provisions of the existing § 5.47 would be moved to § 5.46. The revised section would describe the correct display of the Coast Guard ensign and cross-reference to the official description of the Coast Guard ensign at 33 CFR 23.15.

§ 5.48—Auxiliary patrol boat ensign: We propose to revise this section. Provisions of the existing § 5.48 would be moved to § 5.46. The revised section would describe markings that may be displayed on Auxiliary aircraft.

§ 5.49—Reimbursement for expenses: We propose to remove this section; its provisions would be moved to § 5.30(c).

§ 5.55: We propose to remove this section; its provisions would be consolidated in § 5.16.

§ 5.57: We propose to remove this section; its provisions would be consolidated in § 5.16.

§ 5.59: We propose to remove this section because its provisions would be consolidated in § 5.18.

§ 5.61: We propose to remove this section because its provisions would be consolidated in § 5.14.

§ 5.63: We propose to remove this section because its provisions would be consolidated in § 5.14.

§ 5.65: We propose to remove this section because its provisions (dealing with the eligibility of Auxiliary members for Coast Guard medals and awards) are more appropriately covered in the primary Auxiliary policy reference, the Coast Guard Auxiliary Manual (COMDTINST M16790.1 (series)). Medals and awards are a matter of agency management and agency personnel, and therefore exempt from the Administrative Procedure Act (5 U.S.C. 553(a)(2)).

§ 5.69: We propose to remove this section because it restates, verbatim, language contained in 14 U.S.C. 893.

V. Regulatory Analysis

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Coast Guard has determined that this NPRM is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget. A draft regulatory assessment follows.

The proposed rule would conform regulatory language to statutes, codify many existing practices, clarify procedures, increase procedural flexibility for Coast Guard and Auxiliarists, increase overall efficiency in the process, and re-organize content to improve clarity. There are no costs to either the federal government or the private sector associated with these proposed changes. This notice of proposed rulemaking applies to members and prospective members of the Coast Guard Auxiliary and people and companies that interact with the Auxiliary. The Auxiliary is a Congressionally-chartered component of the Coast Guard made up of civilian volunteers. Auxiliary units (''flotillas'') are neither corporations nor charities and often encounter administrative trouble with banks, insurance companies, and businesses. This rulemaking would clarify for the public the nature, organization, and purpose of the Auxiliary, and conform the regulatory language to the Auxiliary statutes, as amended by legislative

changes. Many of these changes are already reflected in Coast Guard policies and manuals. For example, the financial aspects of these regulations, such as reimbursement of expenses, including the Standard Auxiliary Maintenance Allowance (SAMA), incorporate already existing practices and authorities, as detailed in Auxiliary Manual COMDTINST M16790.1 (series), chapter 9 and Auxiliary Operations Policy Manual COMDTINST M16798.3 (series), chapter 3 and section B–2.

These proposed changes would update our regulations to capture our current practices regarding reimbursement of Auxiliary facility expenses and maintenance costs. The payment of death gratuities to the representatives of Auxiliarists who die in the performance of duty while assigned to duty is currently funded pursuant to legislative authorization and supported by Commandant policy (COMDTINST 12550.21A, CG Death Gratuity Payment), enabling Auxiliarists to be regarded equally as Coast Guard employees for the purpose of death gratuity payments.

The primary benefit of this proposed rule would be to conform regulatory language to the legislative changes described in section III, Background. This would result in increased efficiencies in Auxiliary interactions with the Coast Guard and with the public, including Auxiliarists' interaction with banks and insurance agents. Banks help provide reimbursement (via direct deposit) for operations and other missions requiring Auxiliarists to incur an initial expense from their personal funds. Insurance agents' relationships are also important, as Auxiliarists may be reimbursed for damages to their vessels when those vessels are engaged in waterborne or airborne operational patrols.

We have classified the proposed changes into categories, as listed in Table 2. There are no costs associated with the changes.

TABLE 2—33 CFR PART 5 CATEGORIES AND DISCUSSION OF PROPOSED CHANGES

Proposed section	Category of change	Cost impact	Discussion of proposed changes
§ 5.1	Revise section	None—Administrative revisions made consistent with statutory changes.	Revises the definition of ''Act'' to ''Auxiliary Act'' and to include recent statutory amendments, including Coast Guard Authorization Act of 1996 amendments, the 2002 amendment contained in the Maritime Transportation Security Act of 2002 (Pub. L. 107–295), the 2004 amendment contained in the Coast Guard and Maritime Transportation Security Act of 2004 (Pub. L. 108–293), the 2006 amendments contained in the Coast Guard and Maritime Security Act of 2006 (Pub. L. 109–241) and the 2012 amendments contained the Coast Guard and Maritime Transportation Act of 2012 (Pub. L. 112–213). Added definitions for ''Personal property of the Auxiliary'' and ''Direct law enforcement''. Amended definition for ''Facility or facilities'', ''radio station'' and ''Secretary''.
§ 5.3	Revise section	None—Administrative revisions made consistent with statutory changes.	Discusses Auxiliary purpose and scope of activities to conform to language in 14 U.S.C. 822, as amended in 1996.
§ 5.5	Revise and expand section.	None—Clarification of existing law	Added to clarify non-military nature of Auxiliary and composition of elected and appointed officers.
§ 5.7	Revise section	None	Defines the nature and authority of Auxiliary.
§ 5.9	Revise section	None—Reorganization and revision to reflect current practice.	Existing contents covered in new section § 5.10. New content establishes various Coast Guard directives and publications as appropriate references. Provides details of Auxiliary activities through Source 1: Auxiliary Manual COMDTINST M16790.1 (series) and Source 2: Auxiliary Operations Policy Manual COMDTINST M16798.3 (series).
§ 5.10	Add section	None—Removes Barrier to Entry	New content moved from 5.09 and revised. Eliminates minimum age and ownership requirements to remove unnecessary barriers to entry into Auxiliary. Reflects recent legislative change that authorizes eligibility for Auxiliary members to include United States nationals and aliens lawfully admitted for permanent residence.
§ 5.11	Revise section	None—Reorganization	Existing content removed as redundant of 14 U.S.C. 825; new content moved with minor edits from § 5.25.
§ 5.12	Add section	None—Reorganization	New content moved with minor edits from § 5.21.
§ 5.13	Revise section	None—Reorganization	Existing content covered by § 5.10 and published in the Auxiliary manual COMDT INSTM16790.1 (series), Chapter 3A. New content moved with minor edits from § 5.23.
§ 5.14	Add section	None—Reorganization	New content moved from § 5.61— Uniforms and § 5.63—Insignia and combined. See Source 1 for additional background.
§ 5.15	Reserved	None—Reorganization and Clarification	Existing content moved to § 5.10 and revised for clarity.
§ 5.16	Add section	None—Reorganization	New content moved from § 5.55—Compensation and § 5.57—Traveling expenses and per diem and combined with minor edit.
§ 5.17	Revise section	None—Reorganization and Clarification of Current Practice consistent with statute.	Existing content moved to § 5.19. New content added to clarify the status of Auxiliarists as Federal employees only as provided for by 14 U.S.C. 823a.

TABLE 2—33 CFR PART 5 CATEGORIES AND DISCUSSION OF PROPOSED CHANGES—Continued

Proposed section	Category of change	Cost impact	Discussion of proposed changes
§ 5.18	Add section	None—Clarification of Current Practice	Added to clarify the benefits paid in case of injury or death while assigned to duty. In general, these benefits are currently covered in AFC–08 account for civilian pay. Procedures already in place. See Source One, Chapter 5 Section K: Claims, Injury, or Death while Assigned to Duty and K.6.: Death of an Auxiliarist while Assigned to Duty. No net cost to the Coast Guard or Auxiliary.
§ 5.19	Revise section	None—Reorganization	Existing content moved to § 5.26(b); new content moved from current § 5.17.
§ 5.20	Add section	None—Reorganization, revisions to reflect current practice.	Moved from § 5.31. The Coast Guard would amend this section to remove the word ''specific''. It would also implement current policy on exclusion from law enforcement power and authority of Auxiliarists and recognition that status and authority of Auxiliarists in various duty assignments may be limited beyond that of their regular Coast Guard counterparts.
	Remove § 5.21	None—Reorganization	Moved to § 5.12.
§ 5.22	Add section	None—Reorganization	Existing content moved to § 5.12. New content moved from §§ 5.27 and 5.29 with minimal edits.
	Remove § 5.23	None—Reorganization	Moved to § 5.13.
§ 5.24	Add section	None—Current practice	Added to include information about procedures for assignment to duty of Auxiliarists and their facilities. This section would codify the language in the Auxiliary Manual, based on the 1996 Act.
	Remove § 5.25	None—Reorganization	Moved to § 5.11.
§ 5.26	Add section	None—Reorganization	New content moved from § 5.33. Added minor edited item from § 5.19.
	Remove § 5.27	None—Reorganization	Moved to § 5.22.
	Remove § 5.29	None—Reorganization	Moved to § 5.22.
§ 5.30	Add section	None—Reorganization	New section with clarification of facilities' duty status. Clarification of facilities' liability status, in accordance with 14 U.S.C. 821(d)(2). New section to clarify expense reimbursement using concepts from current § 5.49.
	Remove § 5.31	None—Reorganization	Moved to § 5.20.
§ 5.32	Add section	None—Reorganization	Incorporates provisions of § 5.41.
	Remove § 5.33	None—Reorganization	Moved to § 5.26.
§ 5.34	Add section	None—Clarification of current practice consistent with statute.	This section would be added to address offers of use personal property of the Auxiliary, pursuant to 14 U.S.C. 821. Incorporates provisions of § 5.41.
	Remove § 5.35	None—Reorganization	Incorporated into § 5.36.
§ 5.36	Add section	None—Clarification of current practice	New provision on how member-owned or unit-owned property can be loaned to the Coast Guard (no Auxiliarists onboard). Incorporates provisions from current §§ 5.35, 5.37, 5.39, 5.41, and 5.45.
	Remove § 5.37	None—Reorganization	Incorporated into § 5.36.
	Remove § 5.39	None—Reorganization	Moved without change to § 5.36(b).
§ 5.40	Add section	None—Clarification of current practice	Added this new section on facility markings to ensure clarity for both the Auxiliary and public regarding the identification of Auxiliary vessels, aircraft, motorized vehicles, trailers, radio stations, and other equipment when assigned to Coast Guard duty.
§ 5.41	Revise section	None—Clarification of current practice	Concept of existing section moved to §§ 5.32(c), 5.34(c), and 5.36(c). Added language to describe the Auxiliary emblem and discuss when it can be worn and used. Paragraph (b) moved from section § 5.47(c).
§ 5.42	Add section	None—Clarification of current practice	Content moved from 5.47. Prescribes the use of the Auxiliary ensign in accordance with Auxiliary policy.
§ 5.43	Revise section	None—Current practice	Existing content moved to § 5.30. New content would codify the description of the Auxiliary mark from the Auxiliary Manual.
§ 5.44	Add section	None—Clarification of current practice	Added to prescribe the use of the Auxiliary facility decal as a distinctive marking for vessels, aircraft, and radio stations that have been offered, inspected, and accepted for Coast Guard use.
§ 5.45	Revise section	None—Reorganization and clarification of current practice.	Concept of existing section moved to § 5.36(a). Added new content to describe the use of Auxiliary patrol signs as distinctive markings for vessels, motorized vehicles, and trailers when assigned to duty.
§ 5.46	Add section	None—Clarification of current practice	Added to address the proper use of the Auxiliary patrol boat ensign. Moved part of § 5.48 to this location.

TABLE 2—33 CFR PART 5 CATEGORIES AND DISCUSSION OF PROPOSED CHANGES—Continued

Proposed section	Category of change	Cost impact	Discussion of proposed changes
§ 5.47	Revise section	None—Reorganization and Current practice.	Existing content moved to §§ 5.40, 5.41, and 5.42. New content would codify the display of the Coast Guard ensign as described in Auxiliary policy.
§ 5.48	Revise section	None—Reorganization and clarification of current practice.	Existing content moved to §§ 5.40 and 5.46. New content added to address the additional markings of Auxiliary aircraft. Would reflect the allowance for Auxiliary aircraft to display the Auxiliary facility decal.
	Remove § 5.49	None—Reorganization	Concept moved to § 5.30.
	Remove § 5.55	None—Reorganization	Moved to § 5.16.
	Remove § 5.57	None—Reorganization	Moved to § 5.16.
	Remove § 5.59	None—Reorganization	Moved to § 5.18 (b) and (c) and revised.
	Remove § 5.61	None—Reorganization	Moved to § 5.14.
	Remove § 5.63	None—Reorganization	Moved to § 5.14.
	Remove § 5.65	None—Current Practice	Internal policy in Auxiliary Manual COMDTINST M16790.1 (series) Chapter 11, and in Coast Guard Medals and Awards Manual, COMDTINST M1650.25. See also 14 U.S.C. 502.
	Remove § 5.69	None—Duplicative	Duplicative of 14 U.S.C. 893.

Source 1 Auxiliary Manual COMDTINST M16790.1 (series).
Source 2 Auxiliary Operations Policy Manual COMDTINST M16798.3 (series).

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. 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.

This rule imposes no direct costs; consequently, there are no impacts on small entities to consider.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why you think your business or organization qualifies, how and to what degree this rule would economically affect it.

D. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E. 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 proposed rule under E.O. 13132 and have determined that it does not have implications for federalism under that Order.

F. 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 regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This proposed rule would 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.

H. Civil Justice Reform

This proposed 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.

I. Protection of Children

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

J. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant regulatory action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this proposed 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 made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. This proposed rule involves the operation and administration of the Coast Guard Auxiliary and falls under section 2.B.2, figure 2–1, paragraphs (34)(a), (b), (c), and (d) of the Instruction. These paragraphs exempt regulations which are editorial or procedural, concern internal agency functions or organization, concern the training and qualifying of maritime personnel, and concern the inspection of vessels, respectively. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of subjects in 33 CFR Part 5

Volunteers.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 5 as follows:

Title 33—Navigation and Navigable Waters

PART 5—COAST GUARD AUXILIARY

■ 1. Revise part 5 to read as follows:

Subpart A—General

Sec.
5.1 Definitions.
5.3 Purpose.
5.5 Organization, officers, and leadership.
5.7 Administration, specific authorizations.
5.9 References.

Subpart B—Membership

5.10 Eligibility for membership.
5.11 Honorary members.
5.12 Ranks, titles, designations, or grades.
5.13 Advancement.
5.14 Uniforms and insignia.
5.15 [Reserved]
5.16 Compensation and travel expenses.
5.17 Status of members as Federal employees.
5.18 Injury or death in the line of duty.
5.19 Disenrollment.

Subpart C—Activities, Operations, and Training

5.20 Authority.
5.22 Assignment to duties.
5.24 Procedure for assignment to duty.
5.26 Training, examination, and assignment.

Subpart D—Facilities and other equipment

5.30 Facilities and other equipment.
5.32 Offer of member-owned vessels, aircraft, radio stations, motorized vehicles, trailers, and other equipment for use as a facility.
5.34 Offers of personal property of the Auxiliary as a facility.
5.36 Loan of vessels, aircraft, radio stations, motorized vehicles, trailers, or other equipment to the Coast Guard.

Subpart E—Auxiliary Markings

5.40 Distinctive markings for vessels, aircraft, motorized vehicles, trailers, radio stations, and other equipment.
5.41 Auxiliary emblem.
5.42 Auxiliary ensign.
5.43 Auxiliary mark.
5.44 Auxiliary facility decal.
5.45 Patrol signs.
5.46 Auxiliary patrol boat ensign.
5.47 Coast Guard Ensign.
5.48 Marking of aircraft.

Authority: 14 U.S.C. 633, 821, 822, 823, 823a, 824, 825, 826, 827, 828, 829, 830, 831, 832, 892; Department of Homeland Security Delegation No. 0170.1

Subpart A—General

§ 5.1 Definitions.

Certain terms used in this part are defined as follows:

Aircraft means any contrivance now known or hereafter invented, used, or designed for navigation of or flight in the air.

Auxiliary means the United States Coast Guard Auxiliary established pursuant to the Auxiliary Act.

Auxiliary Act means the laws governing the Coast Guard Auxiliary, codified in chapters 23 and 25 of Title 14, United States Code (14 U.S.C. 821–894).

Commandant means the Commandant of the United States Coast Guard.

Direct Law Enforcement is described in Chapter 4.E. of the Auxiliary Operations Policy Manual, COMDTINST M16798.3E, and includes boarding a vessel for law enforcement purposes, carrying on their person firearms or law enforcement equipment (handcuffs, pepper spray, etc.), investigating complains of negligent operations, serving subpoenas, and covert operations.

Facility or facilities means a vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment accepted for use by the Coast Guard.

Member means any person who is a member of the Auxiliary.

Motorboat means any documented or numbered vessel propelled by machinery, not more than 65 feet in length, measured end-to-end over the deck, excluding sheer.

Personal property of the Auxiliary means a vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment owned by, or under the administrative jurisdiction of, the Coast Guard Auxiliary or an Auxiliary unit, and that is used solely for Auxiliary purposes and in accordance with the Auxiliary Act.

Radio station means any equipment (including a building, recreational vehicle, trailer, or other motorized vehicle which houses such equipment) used for radio communication or direction finding.

Secretary means the Secretary of the Department in which the Coast Guard is operating.

Vessel means a motorboat or yacht.

Yacht means either—

(1) Any documented or numbered vessel used exclusively for pleasure; or

(2) Any sailboat used exclusively for pleasure more than 16 feet in length measured end-to-end over the deck, excluding sheer.

§ 5.3 Purpose.

(a) The Auxiliary is a uniformed, volunteer, non-military organization administered by the Commandant under the direction of the Secretary.

(b) The purpose of the Auxiliary is to assist the Coast Guard, as authorized by the Commandant, in performing any Coast Guard function, power, duty, role, mission, or operation authorized by law.

(c) Auxiliary units may assist the Coast Guard in maintenance and upkeep, and in conducting tours of Coast Guard and other Federal- or State-owned structures and property.

(d) The Auxiliary may assist Federal, State, and municipal agencies, as authorized by the Commandant.

§ 5.5 Organization, officers, and leadership.

(a) The Coast Guard Auxiliary is organized pursuant to the Auxiliary Act and Coast Guard regulations. Organizational elements include a national board and staff, national leadership, areas, districts, regions, divisions, and flotillas. A flotilla is the basic organizational unit of the Auxiliary.

(b) The Auxiliary has elected and appointed officers.

(1) Elected officers are in charge of Auxiliary units and elements at both the national and local levels of the Auxiliary organization. The Unit Leader is the senior elected officer at each level of the Auxiliary organization: Flotilla Commanders, Division Commanders, District Commodores, and the National Commodore are unit leaders.

(2) Appointed officers are appointed by elected officers and hold staff positions in Auxiliary units at both the national and local levels of the Auxiliary organization.

(c) For all Auxiliary units, the Unit Leader is the person authorized to exercise the authority set forth in § 5.07 of this part on behalf of his or her unit, and may delegate that authority.

(d) For all Auxiliary units, the Finance Officer is the person authorized to handle, transfer and disburse bank accounts, monies, stocks, bonds, and other items of intangible personal property on behalf of his or her Auxiliary Unit.

§ 5.7 Administration, specific authorizations.

(a) The Commandant may delegate any authority vested in him by the Auxiliary Act or by this part to personnel of the Coast Guard and members of the Auxiliary in the manner and to the extent as the Commandant deems necessary or appropriate for the functioning, organization, and internal administration of the Auxiliary.

(b) The Commandant has authorized Auxiliary Unit Leaders to take the following actions in furtherance of the authorized missions of the Auxiliary. This is not an exclusive list—

(1) Acquire, own, hold, use, and dispose of vessels, aircraft, motorized vehicles, trailers, radio stations, and electronic equipment and other items of tangible, personal property;

(2) Accept ownership, custody, or use of vessels, boats, aircraft, radio stations, motorized vehicles, trailers, electronic equipment, and other tangible property from the Coast Guard, from other Federal, State, or municipal agencies, or from private or non-profit groups;

(3) Create and manage bank accounts, monies, stocks, bonds, and other financial instruments;

(4) Accept and use gifts, grants, legacies, and bequests;

(5) Accept funds, materials, services, and the use of facilities from public and private entities and Federal, State, or municipal agencies;

(6) Enter into licenses, leases, contracts, memoranda of agreement, or understanding, and other agreements; and

(7) Enter into cooperative agreements and grant agreements with the Coast Guard and other Federal, State, or municipal agencies.

(c) The national board of the Auxiliary may form a corporation under State law and Coast Guard policy to manage the Auxiliary's fiscal affairs. The national corporation may—

(1) Hold copyrights, trademarks, and titles to Auxiliary property;

(2) Contract with the Coast Guard and other Federal, State, and municipal agencies to procure such goods and services;

(3) Receive grants, gifts, and other items on behalf of the Auxiliary; and

(4) Conduct other activities as may be authorized by the Commandant.

(d) An Auxiliary district or region may form a corporation under State law and Coast Guard policy.

§ 5.9 References.

Further guidance on Auxiliary missions and activities may be found in Coast Guard directives and publications, including the Coast Guard Auxiliary Manual (Commandant Instruction M16790.1 (series)) and the Coast Guard Auxiliary Operations Policy Manual (Commandant Instruction M16798.3 (series)). Those directives and publications can be found online at *http://www.uscg.mil/auxiliary/publications/comdtinst/.*

Subpart B—Membership

§ 5.10 Eligibility for membership.

(a) To be eligible for membership in the Auxiliary, a person must be a United States citizen, a national of the United States or of its Territories and possessions, or an alien lawfully admitted for permanent residence; and must meet the standards for enrollment, retention, and conduct established by the Commandant.

(b) An applicant who is accepted for membership will be enrolled in the Auxiliary and will be issued a membership certificate and identification card. Possession of a membership certificate or identification card does not entitle a person to any rights or privileges of the Coast Guard or the Coast Guard Reserve except as authorized by the Commandant.

§ 5.11 Honorary members.

The Commandant may grant any person honorary membership in the Auxiliary. An honorary member of the Auxiliary, solely by reason of such honorary membership, is not entitled to any of the rights, benefits, privileges, duties, or obligations of Auxiliary membership.

§ 5.12 Ranks, titles, designations, or grades.

The members of the Auxiliary will have such ranks, titles, designations, or grades, pursuant to their qualifications, as the Commandant considers necessary.

§ 5.13 Advancement.

The Commandant will prescribe the circumstances and qualifications under which members of the Auxiliary may be advanced in offices and programs.

§ 5.14 Uniforms and insignia.

Members of the Auxiliary may purchase from the Coast Guard such uniforms and insignia as may be authorized by the Secretary. Such uniforms and insignia may be worn by members of the Auxiliary under such circumstances and upon such occasions as may be authorized by the Commandant.

§ 5.15 [Reserved]

§ 5.16 Compensation and travel expenses.

(a) Except as provided in paragraph (b) of this section, no member of the Auxiliary will receive any compensation for services as a member of the Auxiliary.

(b) A member of the Auxiliary may be paid actual necessary travelling expenses, including a per diem allowance.

§ 5.17 Status of members as Federal Employees.

Members of the Auxiliary are not considered Federal employees except as provided by 14 U.S.C. 823a or other provisions of law.

§ 5.18 Injury or death in the line of duty.

(a) The performance of duty, as the term is used in this part, includes time spent in the performance of duty, travel between duty locations, and travel to

and from a place of assigned duty and the permanent residence or other appropriate non-duty destination.

(b) A member of the Auxiliary who incurs physical injury or contracts sickness or disease in the performance of duty is entitled to medical and dental care until the resulting impairment cannot be materially improved by further hospitalization or treatment. A member of the Auxiliary who incurs physical injury or contracts sickness or disease in the performance of duty is entitled to obtain medical care from the Coast Guard, including through Coast Guard arrangements with a contract provider, the Public Health Service, the Department of Defense, or a Veterans' Administration facility.

(c) If a member of the Auxiliary is physically injured or dies as a result of physical injury, and the injury is incurred in the performance of duty, the member or the member's beneficiaries are authorized to receive compensation in accordance with 14 U.S.C. 707, 5 U.S.C. 8133 and 8134 and section 651 of Pub. L. 104–208 (5 U.S.C. 8133 Note).

§ 5.19 Disenrollment.

A member of the Auxiliary will be disenrolled on request, upon ceasing to possess the qualifications for membership, for cause, upon direction of the Commandant, or upon death.

Subpart C—Activities, Operations and Training

§ 5.20 Authority.

(a) Except as provided in paragraphs (b) and (c) of this section, or otherwise limited by the Commandant, members of the Auxiliary assigned to duty will have the same authority in its execution as a member of the regular Coast Guard who is assigned to a similar duty.

(b) Members of the Auxiliary are not authorized to engage in direct law enforcement or military missions.

(c) Members of the Auxiliary are not authorized to enforce limited access areas, regulated navigation areas, or special local regulations. Members of the Auxiliary assigned to patrol limited access areas, regulated navigation areas, or areas regulated under special local regulations may advise the public regarding compliance with the limited access area, regulated navigation area, or areas regulated by special local regulations.

§ 5.22 Assignment to duties.

Members of the Auxiliary will not be assigned duties until they have been found to be competent to perform such duties and have been designated by authority of the Commandant to perform such duties.

§ 5.24 Procedure for assignment to duty.

Members and facilities may be assigned to duty by any of the following procedures:

(a) Verbal or written orders issued by competent Coast Guard authority;

(b) The actual performance of an authorized activity or mission by a qualified member of the Auxiliary; or

(c) Other procedures, as designated by the Commandant.

§ 5.26 Training, examination, and assignment.

(a) The Commandant will prescribe, through the Coast Guard Auxiliary references described in § 5.09 of this part, the type of training, qualifications, and examinations required before a member of the Auxiliary will be deemed qualified to perform certain duties, and will prescribe the circumstances and manner in which members of the Auxiliary will be authorized to perform regular and emergency duties.

(b) The Commandant may authorize members of the Auxiliary to pursue correspondence courses and distance-learning courses conducted by the Coast Guard Institute or other authorized Coast Guard providers and to attend other courses and training available to members of the Coast Guard or Reserve.

Subpart D—Facilities and Equipment

§ 5.30 Facilities and Other Equipment.

(a) This subpart contains regulations related to the facilities and other equipment used by the Auxiliary or loaned by the Auxiliary to the Coast Guard.

(b) *Status.* (1) *Duty.* Personal property of the Auxiliary, except when used for other than Auxiliary purposes in accordance with 14 U.S.C. 822, will be considered assigned to authorized Coast Guard duty at all times.

(2) *Liability.* Personal property of the Auxiliary, except when used for other than Auxiliary purposes in accordance with 14 U.S.C. 822, will be treated as property of the United States for the purposes of the Federal Tort Claims Act, the Military Claims Act, the Public Vessels Act, the Suits in Admiralty Act, the Admiralty Extension Act, and other matters related to non-contractual civil liability. Personal property of the Auxiliary is not normally covered for damage to the property itself.

(3) *Public vessels.* Vessels, aircraft, and radio stations loaned to, or whose custody has been given to, the Auxiliary by the Coast Guard or other Federal agencies remain public vessels of the United States, vessels of the Coast Guard, public aircraft, Coast Guard aircraft, or government stations, as applicable.

(c) *Expenses.* (1) The Coast Guard may reimburse expenses related to the use, operation, or maintenance of a facility.

(2) The Coast Guard may reimburse expenses for damage or loss to or by a facility, including remediation, restoration, repair, replacement, or salvage costs.

(3) The Coast Guard may provide an allowance for the maintenance of a facility.

§ 5.32 Offers of member-owned vessels, aircraft, radio stations, motorized vehicles, trailers, and other equipment for use as a facility.

(a) Members of the Auxiliary wishing to offer vessels, aircraft, radio stations, motorized vehicles, trailers, or other equipment for use as a facility must follow the procedures set forth in the Auxiliary Operations Policy Manual described in § 5.09 of this part.

(b) Upon acceptance of the vessels, aircraft, radio stations, motorized vehicles, trailers, or other equipment as a facility, the Coast Guard will issue to the member the appropriate numbers and decals identifying the facility as a Coast Guard Auxiliary facility.

(c) In an emergency, vessels, aircraft, radio stations, motorized vehicles, trailers, or other equipment may be accepted by the Coast Guard without an inventory or the use of the prescribed forms.

§ 5.34 Offers of personal property of the Auxiliary for use as a facility.

(a) Auxiliary units wishing to offer personal property of the Auxiliary (usually unit-owned property) for use as a facility must follow the procedures set forth in the Auxiliary Operations Policy Manual described in § 5.09 of this part.

(b) Upon acceptance of the personal property of the Auxiliary as a facility, the Coast Guard will issue to the Auxiliary unit the appropriate numbers and decals identifying the facility as a Coast Guard Auxiliary facility.

(c) In an emergency, personal property of the Auxiliary may be accepted by the Coast Guard without an inventory or the use of prescribed forms.

§ 5.36 Loan of vessels, aircraft, radio stations, motorized vehicles, trailers, or other equipment to the Coast Guard.

(a) A vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment may be loaned to the Coast Guard for a specific period, and must be returned at the expiration of that period, unless circumstances or an emergency make the return impracticable at that time. The Commandant will determine the method, time, and documents to be exchanged upon the return to the owner of any facility. The property will be re-

inventoried as of the time, date, and place of re-delivery, and mutually settled by the owner and the Coast Guard representative. If the vessel was accepted during an emergency, any claim for lost equipment or stores must be supported by invoices showing the date of purchase and the cost thereof by the person submitting the claim. The Coast Guard representative will take all proper precautions to protect the owner's interest, as well as that of the United States.

(b) Except as permitted in paragraph (c) of this section, no vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment will be deemed loaned to the Coast Guard until an acceptance, on the prescribed form, has been signed on behalf of the Coast Guard by a person authorized by the Commandant to sign such an acceptance and a complete inventory of consumable and expendable stores and equipment has been made and mutually settled by the owner and the Coast Guard representative.

(c) In an emergency, a vessel, aircraft, radio station, motorized vehicle, trailer, or other equipment may be loaned to Coast Guard without an inventory or the use of the prescribed form.

Subpart E—Auxiliary Markings

§ 5.40 Distinctive markings for vessels, aircraft, motorized vehicles, trailers, radio stations, and other equipment.

(a) This subpart establishes regulations for the display of distinctive markings of vessels, aircraft, motorized vehicles, trailers, radio stations, and other equipment used by the Auxiliary.

(b) *Auxiliary markings on vessels, aircraft, motorized vehicles, trailers, radio stations and other equipment.* (1) Vessels, aircraft, motorized vehicles, trailers, and radio stations or other equipment which are owned by Auxiliary members, or are personal property of the Auxiliary, or are otherwise affiliated with the Auxiliary may display the Auxiliary Emblem (§ 5.41), the Auxiliary Ensign (§ 5.42), and/or the Auxiliary Mark (§ 5.43).

(2) Vessels, aircraft, motorized vehicles, trailers, radio stations or other equipment which have been accepted as Auxiliary facilities shall display the Auxiliary Facility Decal (§ 5.44).

(3) Facilities which are assigned to Coast Guard duty shall display the National Ensign, the Patrol Sign (§ 5.45) and either the Patrol Boat Ensign (§ 5.46) or the Coast Guard Ensign (§ 5.47) as appropriate and able.

(4) Facilities which are assigned to Coast Guard duty and have a Coast Guard commissioned, warrant, or non-commissioned officer onboard may display the Coast Guard Ensign in place of the Patrol Boat Ensign.

(c)(1) Any person who desires to reproduce Coast Guard Auxiliary markings for non-Coast Guard Auxiliary use must obtain approval from the U.S. Coast Guard Auxiliary Division (CG–BSX–1), 2100 2nd St. SW., Stop 7581, Washington, DC 20593–7581.)

(2) Unauthorized use of Auxiliary markings is subject to the penalties of 14 U.S.C. 638, 639 and 892.

§ 5.41 Auxiliary emblem.

(a) *Description.* The Auxiliary emblem consists of a disk with the shield of the Coat of Arms of the United States circumscribed by an annulet edged and inscribed ''U.S. COAST GUARD AUXILIARY'', all in front of two crossed anchors.

(b) *Display.* The Auxiliary emblem is used as identification on Auxiliary ensigns, flags, pennants, decals, and patrol signs. The emblem is used on Auxiliary insignia, such as the member collar device, cap device, and Auxiliary aviator, coxswain, and Auxiliary Operator (AUXOP) devices, and on publications, stationery, clothing, and jewelry.

§ 5.42 Auxiliary ensign.

(a) *Description.* The field of the Auxiliary ensign is medium blue (Coast Guard blue) with a broad diagonal white slash upon which a matching blue Coast Guard Auxiliary emblem is centered. The white slash must be at a 70 degree angle, rising away from the hoist.

(b) *Display.* The Coast Guard Auxiliary ensign may be displayed by any member of the Auxiliary on a vessel, aircraft, radio station, building, or other location at any time, under such conditions as the Commandant may direct.

§ 5.43 Auxiliary mark.

(a) *Description.* The Auxiliary mark consists of a broad diagonal blue stripe followed (to the left or aft) by two narrow stripes—first a white stripe, and then a red stripe. The Auxiliary emblem, as described in § 5.41 of this subpart, is centered in the diagonal blue stripe.

(b) *Display.* The Auxiliary identifying mark is used to identify personal property of the Auxiliary and on Coast Guard Auxiliary authorized publications, stationery, jewelry, and similar items.

§ 5.44 Auxiliary facility decal.

(a) *Description.* The Auxiliary facility decal is composed of two parts. The upper part is a conventional white shield with a medium blue (Coast Guard blue) Coast Guard Auxiliary emblem centered on a broad diagonal red (Coast Guard red) slash which is at a 70 degree angle, rising toward the hoist. The red (Coast Guard red) slash is followed, away from the hoist, by two narrow, parallel stripes—first a white stripe, and then a medium blue (Coast Guard blue) stripe. The entire design is centered on the shield. The lower part displays two laterally radiating wreath branches centered immediately beneath the shield. A broad diagonal red (Coast Guard red) slash, which is at a 70 degree angle, rising toward the hoist and followed, away from the hoist, by two narrow, parallel stripes, first a white stripe and then a medium blue (Coast Guard blue) stripe, is displayed on the wreath's right-hand branch.

(b) *Display.* Vessels, aircraft, and radio stations that are accepted for use by the Coast Guard must display the Auxiliary facility decal as authorized in the Auxiliary Operations Policy Manual described in § 5.09 of this part.

(1) On vessels, the decal must be displayed on the port side of the vessel so as to be visible by another vessel when meeting such vessel in a port-to-port situation.

(2) On aircraft, the decal must be displayed on the pilot's side of the forward half of the aircraft.

(3) On radio facilities, the miniature decal must be displayed on the radio, on the exterior or interior of the building or trailer in which the radio is housed, or, in the case of mobile radios, on any legal place on the motor vehicle in which the radio is contained.

§ 5.45 Patrol sign.

(a) *Description.* The Auxiliary facility patrol sign has the words ''Coast Guard Auxiliary Patrol'' in black or dark blue lettering and must contain the Auxiliary emblem, as described in this subpart, centered within the confines of a broad diagonal red (Coast Guard red) stripe which is at a 70 degree angle rising toward the bow of the vessel. The red (Coast Guard red) stripe is followed, away from the bow, by two narrow, parallel stripes—first a white stripe, and then a medium blue (Coast Guard blue) stripe. The background of the sign must be white.

(b) *Display.* (1) The patrol sign must be displayed by vessels while assigned to Coast Guard duty.

(2) The patrol sign must be displayed on the forward half of each side and may be displayed on the stern of the vessel.

(3) The patrol sign may be displayed on each side of a motorized vehicle or trailer containing a mobile radio or

radio direction finding unit while assigned to Coast Guard duty. Normally, they will be placed in any legal position on the upper half of both sides of the vehicle.

§ 5.46 Auxiliary Patrol Boat ensign.

(a) *Description.* The field of the Auxiliary Patrol Boat ensign is white. A medium blue (Coast Guard blue) Coast Guard Auxiliary emblem is centered on a broad diagonal red (Coast Guard red) slash which is at a 70 degree angle, rising toward the hoist. The red (Coast Guard red) slash is followed, away from the hoist, by two narrow, parallel stripes—first a white stripe, and then a medium blue (Coast Guard blue) stripe. The entire design is centered on the ensign.

(b) *Display.* The Auxiliary Patrol Boat Ensign is flown on vessel facilities when assigned to Coast Guard duty. The Auxiliary patrol boat ensign must be displayed at the mast head or from the most conspicuous hoist.

§ 5.47 Coast Guard Ensign

(a) Description. The Coast Guard ensign is described in 33 CFR 23.15.

(b) Display. The Coast Guard ensign may be displayed in place of the Auxiliary patrol boat ensign on a vessel while it is assigned to Coast Guard duty and has a Coast Guard commissioned, warrant, or non-commissioned officer onboard. The Coast Guard ensign must be displayed at the mast head or from the most conspicuous hoist.

§ 5.48 Marking of aircraft.

(a) Aircraft owned by members of the Auxiliary or that are personal property of the Auxiliary may also display the Auxiliary emblem on both sides of the vertical stabilizer (outside of the stabilizer for twin tail aircraft) or on both sides of the fuselage aft of the wing.

(b) Aircraft which have been accepted as facilities may be marked with the Auxiliary Mark (§ 5.43) and/or the word ''RESCUE'' on the underside of the wing or fuselage for easier identification from the ground.

Dated: April 30, 2013.

Paul F. Thomas,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2013–10882 Filed 5–9–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 101, 104, 105, and 106

[Docket No. USCG–2007–28915]

RIN 1625–AB21

Transportation Worker Identification Credential (TWIC)—Reader Requirements

AGENCY: Coast Guard, DHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Coast Guard is extending the comment period for the notice of proposed rulemaking (NPRM) published March 22, 2013, entitled ''Transportation Worker Identification Credential (TWIC)—Reader Requirements'' for 30 days. This extension of the comment period is designed to accommodate requests from the public for more time to review the proposed rule and associated analysis.

DATES: The comment period for the proposed rule published March 22, 2013, at 78 FR 17781, is extended. Comments and related material must be submitted to the docket by June 20, 2013.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Fax:* 202–493–2251.
- *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Loan T. O'Brien, U.S. Coast Guard, telephone 202–372–1133, email *Loan.T.O'Brien@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2007–28915) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

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 the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2007–28915) 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.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

B. Regulatory History and Information

The Coast Guard published an NPRM entitled ''Transportation Worker Identification Credential (TWIC)—Reader Requirements'' on March 22, 2013 (78 FR 17782) that proposes to require owners and operators of certain vessels and facilities regulated by the Coast Guard to use electronic readers designed to work with the Transportation Worker Identification Credential (TWIC) as an access control measure. The NPRM also proposes additional requirements associated with electronic TWIC readers, including recordkeeping requirements for those owners and operators required to use an electronic TWIC reader, and security plan amendments to incorporate TWIC requirements. The TWIC program, including the proposed TWIC reader requirements in the proposed rule, is an important component of the Coast Guard's multi-layered system of access control requirements and other measures designed to enhance maritime security. All comments on this NPRM were originally due on May 21, 2013.

C. Background and Purpose

The Coast Guard believes that the public would benefit from additional time to provide comments on the proposed rule and analysis. For that reason, we are extending the comment period for a period of 30 days. Comments on the NPRM will now be accepted until June 20, 2013.

D. Authority

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: May 3, 2013.

Paul F. Thomas,

Director of Inspections and Compliance, U.S. Coast Guard.

[FR Doc. 2013–11227 Filed 5–8–13; 11:15 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2013–0252]

RIN 1625–AA09

Drawbridge Operation Regulation; Wolf River, Gills Landing and Winneconne, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise the operating schedule that governs the Winneconne Highway Bridge at Mile 2.4, and the Canadian National Railroad Bridge at mile 27.8, both over the Wolf River. A review of the current regulation was requested by the Wisconsin Department of Transportation (WDOT) and the Canadian National Railroad.

DATES: Comments and related material must reach the Coast Guard on or before June 10, 2013.

ADDRESSES: You may submit comments identified by docket number USCG–2013–0252 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. To avoid duplication, please use only one of these four methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Lee Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone (216) 902–6085, email *Lee.D.Soule@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking
§ Section Symbol
U.S.C. United States Code

A. Public Participation and Request for Comments

We encourage you to participate in this proposed rulemaking by submitting comments and related materials. All comments received will be posted, without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this proposed rulemaking (USCG–2013–0252), 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 (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, type the docket number [USCG–2013–0252] in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking. 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 them 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 the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type the docket number (USCG–2013–0252) 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.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before May 30, 2013 using one of the four methods specified under **ADDRESSES**. Please explain why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

The existing regulation for Wolf River (33 CFR 117.1107) addresses only one of the two drawbridges over Wolf River, and has not been revised since the overall recodification of federal drawbridge regulations in 1984.

This proposed rule was developed in conjunction with locally applied bridge schedules implemented by WDOT and Fox River Valley Navigation Authority for the past 10 to 15 years. These agencies, along with Canadian National Railroad, have reviewed and approved this proposed rule.

C. Basis and Purpose

The Wolf River extends from its head of navigation in New London, WI and travels south to Winneconne, WI where it confluences with the Upper Fox River. The Wolf River has two drawbridges over the waterway. The Winneconne Highway Bridge at mile 2.4 is a bascule bridge that provides 70 feet horizontal clearance, 7 feet vertical clearance in the closed position, and an unlimited vertical clearance in the open position. The Canadian National Railroad Bridge at Mile 27.8 is a former swing bridge that was converted to a vertical lift bridge in 2012 that provides 56 feet horizontal clearance, 7 feet vertical clearance in the closed position, and a vertical clearance of 16 feet in the raised position. Marine traffic on the waterway consists of small commercial vessels, and both power and sail recreational vessels. The Coast Guard has been advised of the updated navigation needs on Wolf River, including reports there has been an increase in recreational vessel usage of the waterway due to improvements to the lock system, dredging projects, and restored drawbridges over the Fox River that connect directly with the Wolf River. The purpose of this proposed rule is to establish consistent operating schedules that will meet the needs of current and future navigation on the Wolf River and to provide consistency in regulations for the rest of the connecting waterways.

D. Discussion of Proposed Rule

The current regulation does not include the Canadian National Railroad Bridge. Bridge logs were not available for review. The Coast Guard has made inquiries to local marinas and the Fox River Valley Navigation Authority and determined a 6-hour advance notice for the Canadian National Railroad Bridge from April 20 to October 15 would meet the needs of current navigation since the vertical clearance allows most of the vessel traffic to pass under the bridge without an opening. The Canadian National Railroad Bridge is in a remote location and the only access to the bridge by the drawtender is by boat. A 12-hours advance notice from October 16 to April 19 would be required for openings.

Currently, the Winneconne Bridge opens on signal between the hours of 7 a.m. and 11 p.m., daily, and requires a 2-hour advance notice of arrival for openings from May 1 to October 31 between the hours of 11 p.m. to 7 a.m., daily. From November 1 to April 30 mariners are required to provide a 12-hour advance notice for openings. WDOT has operated the Winneconne Highway Bridge during the navigation season in recent years from April 20 to October 7, with 2-hours advance notice between midnight and 8 a.m. Slight adjustments were made in the development of this proposed rule. Bridge openings on signal are proposed from April 20 through October 15, except from midnight to 8 a.m. when 2-hours advance notice is required for openings.

E. Regulatory Analyses

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

1. Regulatory Planning and Review

This proposed 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 Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This proposed rule incorporates the locally applied bridge schedules that have been employed in recent years, with only small variations. The proposed schedule was reviewed and approved by the bridge owners and representatives of local boating organizations. This proposed rule is expected to improve access to the waterway and establish operating regulations that meet the needs of the boating public in an easy to read language.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels needing to transit the Winneconne Bridge from midnight to 8 a.m. will need to provide a 2-hour advance notice of arrival for bridge openings, and at all hours a 6-hour advance notice for openings at the Canadian National Railroad Bridge. These operating hours would affect both drawbridges throughout the boating season from April 20 to October 15. Impacts to small entities are not expected to be significant as these schedules have effectively been in place for numerous years and are accepted by local vessel operators. During the winter when the waterway is typically ice covered, mariners will be required to provide a 12-hour advance notice for openings for

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

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 proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule would call for no 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 proposed rule under that Order and have determined that it 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 proposed 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 proposed rule would 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This proposed rule 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 proposed 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 guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.1107 to read as follow:

§ 117.1107 Wolf River.

(a) The draw of the Winneconne Highway bridge, mile 2.4 at Winneconne, shall open on signal; except that, between the hours of midnight and 8 a.m., from April 20 through October 15, at least 2-hours of advance notice is required, and from October 16 through April 19, at least 12-hours of advance notice is required. Advance notice shall be provided to the Winnebago County Highway Department.

(b) The draw of the Canadian National Railroad Bridge, mile 27.8 at Gill's Landing, shall open on signal if at least 6-hours advance notice is provided from April 20 through October 15, and if at least 12-hours advance notice is provided from October 16 through April 19.

Dated: April 26, 2013.

M. N. Parks,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2013–11134 Filed 5–9–13; 8:45 am]

BILLING CODE 9110–04–P

LEGAL SERVICES CORPORATION

45 CFR Part 1614

Private Attorney Involvement

AGENCY: Legal Services Corporation.

ACTION: Notice of rulemaking workshops and request for expressions of interest in participating in the rulemaking workshops.

SUMMARY: The Legal Services Corporation (LSC) is conducting two Rulemaking Workshops (Workshops) and is requesting public comments on revising LSC's Private Attorney Involvement (PAI) rule to respond to Recommendation 2 of LSC's Pro Bono Task Force Report. The discussions in the Workshops and the other comments received will be considered in connection with rulemaking by LSC. LSC solicits expression of interest in participating as a panelist in the Workshops from the recipient community, the organized bar, pro bono organizations, and other interested parties.

DATES: Expressions of interest in participating as a panelist must be received by 5:30 p.m. EDT on June 25, 2013 for the first Workshop, and August 20, 2013 for the second Workshop. Written comments recommending additions, deletions, or modifications to the Topics for Discussion, including relevant alternatives, in the Workshops, or written comments on revising LSC's PAI rule, 45 CFR part 1614, to respond to Recommendation 2 of LSC's Pro Bono Task Force Report must be received by 5:30 p.m. EDT on June 25, 2013 for consideration for discussion at the first Workshop, and August 20, 2013 for the second Workshop. The final agenda for the first Workshop will be published on July 18, 2013, and on September 12, 2013 for the second Workshop. All written comments on revising the PAI rule, 45 CFR part 1614, must be received by 5:30 p.m. EDT on October 17, 2013.

ADDRESSES: Written comments submitted to LSC must be in .pdf format (if submitted electronically) and sent to *PAIRULEMAKING@lsc.gov*. If submitted via facsimile, or in hard copy, please address the comments to Mark Freedman, Senior Assistant General Counsel, Legal Services Corporation, 3333 K St NW., Washington, DC 20007; (202) 337–6519 (fax). Written comments sent by any other means, or received after the end of the comment period, may not be considered by LSC.

FOR FURTHER INFORMATION CONTACT: Mark Freedman, Senior Assistant General Counsel, Legal Services Corporation, 3333 K St. NW., Washington, DC 20007; (202) 295–1500 (phone); 202–337–6519 (fax); or *PAIRULEMAKING@lsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

On January 26, 2013, the LSC Board of Directors (LSC Board) voted to authorize LSC to initiate rulemaking to consider revisions to 45 CFR part 1614, Private Attorney Involvement (PAI rule) to respond to Recommendation 2 of LSC's Pro Bono Task Force, available at *http://www.lsc.gov/sites/default/files/LSC/lscgov4/PBTF_%20Report_FINAL.pdf*. The recommendation suggests LSC should reexamine the regulation in three areas:

1. Resources spent supervising and training law students, law graduates, deferred associates, and others should be counted toward grantees' PAI obligations, especially in ''incubator'' initiatives;

2. Grantees should be allowed to spend PAI resources to enhance their screening, advice, and referral programs that often attract pro bono volunteers while serving the needs of low-income clients; and

3. LSC should reexamine the rule that mandates adherence to LSC grantee case handling requirements including that matters be accepted as grantee cases in order for programs to count toward PAI requirements.

On April 14, 2013, the LSC Board voted to convene two Workshops in connection with the rulemaking. The Workshops will be held as a Web-broadcast via Internet connection (Webinar) from LSC's Board meeting in Denver, Colorado on July 23, 2013, at the Warwick Denver Hotel, 1776 Grant St., Denver, Colorado 80203 from 1:30 p.m.–4:30 p.m. MDT, and on September 17, 2013, at the F. William McCalpin Conference Center, Legal Services Corporation Headquarters, 3333 K Street NW., Washington, DC 20007, from 1:30 p.m.–4:30 p.m. EDT. Participants are invited to attend in person, via Webinar, or telephonically via a conference bridgeline. Information about how to participate is available on LSC's Web site at *http://www.lsc.gov/information-rulemaking-workshops-re-lscs-private-attorney-involvement-pai-regulation-and-request*.

II. Nature of the Workshops

Rulemaking workshops enable LSC to meet with interested parties to discuss, but not negotiate, LSC rules and regulations. The Workshops for the PAI rule will be meetings at which the panelists and participants hold open discussions to share ideas regarding how to revise the PAI rule in a manner responsive to the Recommendation 2 of LSC's Pro Bono Task Force Report.

III. Public Participation: Panelists and Open Comment

LSC is inviting expressions of interest from the public to participate in either or both Workshops as a panelist. Expressions of interest in participating as a panelist should be submitted, in writing, to Mark Freedman, Senior Assistant General Counsel, Legal Services Corporation; via email to *PAIRULEMAKING@lsc.gov;* via fax to 202–337–6519; or by hard copy mailed to 3333 K Street NW., Washington, DC 20007. All expressions of interest for the first Workshop must be received by 5:30 p.m. EDT on June 25, 2013 and August 20, 2013 for the second Workshop. LSC will select panelists shortly thereafter and will inform all those who expressed interest whether or not they have been selected.

The Workshops will be open to public observation, and portions of the Workshop will be open for public comment from in-person, Webinar, and telephone participants. Prior to the meeting, participants will be asked to register with LSC to ensure that sufficient arrangements can be made for their participation. Panelists and in-person participants are expected to cover their own expenses (travel, lodging, etc.). LSC may consider providing financial assistance to a panelist for whom travel costs would represent a significant hardship and barrier to participation. Any such person should so note in his/her expression of interest for LSC's consideration.

Through this notice, LSC is also opening a written comment period. LSC welcomes written comments during the comment period outlined below, under Submission of Comments, and will consider the comments received in the rulemaking process.

IV. Topics for Discussion

The following three topics and items for discussion will be addressed during the Workshops and are the subjects on which LSC seeks written comments. Each topic is directly from Recommendation 2 of LSC's Pro Bono Task Force Report. Members of the public are welcome to recommend additions, deletions, or modifications to these Topics for Discussion, including relevant alternatives, for LSC's consideration through written comment prior to the Workshops or by participation in the first Workshop.

Workshop panelists, and those wishing to make comments, may find

additional background information on each of these topics on the designated Workshops Web site at *http://www.lsc.gov/information-rulemaking-workshops-re-lscs-private-attorney-involvement-pai-regulation-and-request*.

Topic 1: LSC Pro Bono Task Force Recommendation 2(a)—Resources spent supervising and training law students, law graduates, deferred associates, and others should be counted toward grantees' PAI obligations, especially in ''incubator'' initiatives.

The Pro Bono Task Force identified several categories of pro bono volunteers as potential resources for LSC recipients to expand in the delivery of legal assistance. The Task Force noted that the LSC definition of ''staff attorney,'' which is based on a compensation scheme standard, is a barrier to full engagement by recipients of deferred associates, law students, and recent law school graduates. LSC welcomes a full discussion of engaging new categories of pro bono volunteers and of improvements to the PAI regulation that would facilitate that engagement.

Items for Discussion on Topic 1:

- How are legal service providers engaging new categories of volunteers? What are the needs of these new categories of volunteers?
- What are the obstacles to LSC grant recipients' full use of these volunteers?
- Should LSC implement conditions and guidelines to allow LSC recipients to claim PAI credit for the supervision and training of these volunteers?
- How can LSC ensure against fraud, waste, or abuse related to implementing this recommendation? What caution should LSC exercise to ensure against any unintended consequences?
- To the extent applicable, discuss how any approaches you recommend might be implemented.

Topic 2: LSC Pro Bono Task Force Recommendation 2(b)—Grantees should be allowed to spend PAI resources to enhance their screening, advice, and referral programs that often attract pro bono volunteers while serving the needs of low-income clients.

The Pro Bono Task Force identified the benefits of integrated intake and referral systems that link clients to volunteer attorneys. Resources used by recipients to staff these integrated systems have not traditionally been recognized as eligible for PAI funds. LSC welcomes a full discussion of the relationship between integrated intake and referral systems that link clients with pro bono volunteers and the use of PAI funds.

Items for Discussion on Topic 2:

- How are recipients currently using integrated intake and referral systems?
- Do LSC's current PAI regulations inhibit full use of integrated intake and referral systems?
- Should LSC implement conditions and guidelines to allow LSC recipients to claim PAI credit for the resources used to create and staff integrated intake and referral systems?
- How can LSC ensure against fraud, waste or abuse related to implementing this recommendation? What caution should LSC exercise to ensure against any unintended consequences?
- To the extent applicable, discuss your organization's ability to execute any recommended approaches.

Topic 3: LSC Pro Bono Task Force Recommendation 2(c)—LSC should reexamine the rule, as currently interpreted, that mandates adherence to LSC grantee case handling requirements, including that matters be accepted as grantee cases in order for programs to count toward PAI requirements.

The Pro Bono Task Force encouraged brief service clinics in which pro bono volunteers rely on LSC recipients to provide technical assistance, research, advice, and counsel to the volunteers. If the recipient is not providing the client service, but is providing training to pro bono volunteers, the Pro Bono Task Force recommended that the resources the recipient uses to support the training be an eligible use for PAI funds, without obligating the pro bono volunteers to screen clients for LSC eligibility or requiring the recipient accept the people served by the clinics as its own clients. LSC welcomes a full discussion of the use of pro bono volunteers in such clinics and invites input on improvements to the existing regulations to facilitate such use.

Items for Discussion on Topic 3:

- How are recipients currently using or supporting pro bono volunteers in brief service clinics?
- What are the obstacles to recipients' use of pro bono volunteers in brief service clinics?
- Should LSC implement conditions and guidelines to allow LSC recipients to claim PAI credit for the resources used to support volunteer attorneys staffing brief service clinics?
- If LSC were to allow recipients to claim PAI credit for the resources used to support volunteer attorneys staffing brief service clinics under circumstances where the users of the clinics are not screened for LSC eligibility or accepted as clients of the recipient, how could that change be implemented in a manner that ensures compliance with legal restrictions on recipients' activities and uses of LSC funds?
- How can LSC ensure against fraud, waste or abuse related to implementing this recommendation? What caution should LSC exercise to ensure against any unintended consequences?
- To the extent applicable, discuss your organization's ability to execute any recommended approaches.

V. Submission of Comments

Members of the public are invited to submit recommended additions, deletions, or modifications to the above described Topics for Discussion, including relevant alternatives, for LSC's consideration, through written comment prior to the Workshops, or by participation in the first Workshop.

Written comments received prior to the Workshops may be addressed in the Workshops. Written comments are requested by June 25, 2013 for LSC to consider including in the first Workshop discussion, and August 20, 2013 for the second Workshop discussion.

Format of the Workshops

LSC plans to host two Workshops to maximize the opportunity for participation. Both of the meetings will include a panel discussion of the Topics for Discussion in this notice. The first Workshop will also include discussion of any recommendations for additions, deletions, or modifications of these Topics for Discussion. Panelists will be selected to represent a diversity of opinions and perspectives.

In addition to the panel, LSC encourages observation and participation by all interested individuals and organizations. The meeting agenda will include opportunities for individuals in attendance who are not members of the panel to participate in person, by webinar, or via telephone, as well as incorporating previously submitted written comments by those unable to attend. LSC plans to transcribe the meetings and make the webinar available on its Web site.

LSC has developed a designated Web site for the purposes of these Workshops and will update it as information becomes available. The final agenda for the Workshops will be available on the LSC Web site for the Workshops approximately five days prior. The Web address is *http://www.lsc.gov/information-rulemaking-workshops-re-lscs-private-attorney-involvement-pai-regulation-and-request*.

VI. Important Notes

Information received in response to this Notice of Rulemaking Workshops and Request for Expressions of Interest in Participation in the Rulemaking Workshops may be published or summarized by LSC without acknowledgement of or permission from you or your organization. Furthermore, your responses may be releasable to the public under the LSC's adoption of the Freedom of Information Act (FOIA), 42 U.S.C. 2996d, and the LSC FOIA regulation, 45 CFR part 1619. LSC, at its discretion, may request individual commenters to elaborate on information in their written comments.

Comments sent by any method other than email to *PAIRULEMAKING@lsc.gov,* or hard copy to Mark Freedman, Senior Assistant General Counsel, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007, or received after the end of the comment period, may not be considered by LSC.

Dated: May 6, 2013.

Atitaya C. Rok,

Staff Attorney.

[FR Doc. 2013–11071 Filed 5–9–13; 8:45 am]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

45 CFR Part 1614

Restrictions on Legal Assistance With Respect to Criminal Proceedings in Tribal Courts

AGENCY: Legal Services Corporation.

ACTION: Request for information.

SUMMARY: The Legal Services Corporation (LSC) is requesting public comments on issues associated with amending its regulations to align with the statutory authority granted to LSC under the Indian Arts and Crafts Amendment Act of 2010 (the IACAA). The IACAA amended the LSC Act to provide authority for LSC funds to be used by grantees to represent eligible persons in any and all criminal proceedings in tribal courts. Previously, the LSC Act and related regulations permitted representation only in criminal matters involving misdemeanors or lesser offenses in tribal courts. The information received as a result of this request will be considered in rulemaking undertaken by LSC.

DATES: Written comments must be received by August 23, 2013.

ADDRESSES: Written comments must be submitted by mail, fax, or email to Atitaya Rok at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Atitaya Rok, Staff Attorney, Legal Services Corporation, 3333 K St. NW., Washington, DC 20007; (202) 295–1500 (phone); 202–337–6831 (fax); or *lscrulemaking@lsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

A. New Statutory Authorities

The IACAA amended the LSC Act to provide authority for LSC funds to be used by grantees to represent eligible persons in any and all criminal proceedings in tribal courts. Previously, the LSC Act and related regulations in 45 CFR part 1613 permitted representation only in criminal matters involving misdemeanors or lesser offenses in tribal courts.

A subsection of the IACAA, known as the Tribal Law and Order Act of 2010, Public Law 111–211, tit. II, 124 Stat. 2261 (the TLOA), includes new authorizations related to tribal court criminal proceedings. The TLOA increases the maximum jail sentence that any tribal court may impose from one to three years for any single offense. Prior to the TLOA, crimes (felonies, misdemeanors, or less serious offenses) within tribal jurisdiction (those not reserved to federal or state jurisdiction) that could result in jail sentences of more than one year upon successful prosecution were often referred by tribes to federal or state courts because of the tribal courts' inability to impose lengthier sentences.

In order to use this new sentencing authority, tribes must ''opt in'' and implement affirmative preconditions detailed in the TLOA, including, but not limited to, ensuring that judges in tribal courts have sufficient legal training to preside over criminal proceedings; affording the defendant the right to effective assistance of counsel and, if a defendant is indigent, providing the defendant with a licensed defense attorney at the tribe's expense; publishing the tribal government's criminal laws and rules of evidence and criminal procedure; and creating a system that maintains records of criminal proceedings. Public Law 111–211, tit. II, 124 Stat. at 2280.

In addition to the IACAA and TLOA, the Violence Against Women Reauthorization Act of 2013, Public Law 113–4, 127 Stat. 54 (the 2013 VAWA expands tribal courts' criminal jurisdiction to include crimes of domestic violence and dating violence committed by non-Indians within a tribal court's jurisdiction.

B. Current LSC Requirements

LSC regulations currently reference the original language of the LSC Act, which explicitly carved out an exception to the general prohibition on the use of LSC funds in criminal proceedings for misdemeanors and lesser offenses in tribal courts: ''[a] misdemeanor or lesser offense tried in an Indian tribal court is not a 'criminal proceeding.'' 45 CFR 1613.2.

On November 12, 2012, LSC Management informed grantees via Program Letter 12–3 that all grantees may use LSC funds to assist any eligible person charged with any offense in a criminal proceeding in a tribal court until such time the LSC Board of Directors (LSC Board) made an affirmative decision on the issue.

On January 26, 2013, the LSC Board authorized rulemaking to consider aligning the LSC regulations and the LSC Act. Pursuant to LSC's Rulemaking Protocol, 67 FR 69763 (Nov. 19, 2002), a Rulemaking Options Paper (ROP) is under development. This Request for Information (RFI) is issued to better understand the impact of the IACAA, TLOA, and the 2013 VAWA on grantees that are active in tribal courts.

II. Request for Information

LSC requests information from members of the public with any expertise or experience relating to criminal proceedings in tribal courts, the impact of TLOA or the 2013 VAWA on criminal laws of tribal government, or tribal court appointments of lawyers. Commenters are asked to respond to these general topics of discussion:

1. Do you or your organization currently undertake representations of criminal defendants in tribal courts?

a. If yes, please identify which tribal courts.

b. If no, do you or your organization have a formal or informal policy in place to provide or decline such representations?

c. Are you or your organization aware of any changes in the criminal laws of the tribal government and/or sentencing authority of the tribal courts that have been implemented in accordance with TLOA or the 2013 VAWA?

2. Do you or your organization anticipate undertaking representations of criminal defendants in tribal courts in the future?

a. If yes, please identify which tribal courts.

b. If no, will you or your organization create a formal or informal policy to provide or decline such representations?

3. As a result of the IACAA, TLOA, and the 2013 VAWA, have you or your organization seen an increase in the number of requests for assistance in criminal matters before tribal courts by eligible clients?

a. If yes, please estimate the number of cases and the approximate percentage these cases constitute as a proportion of all requests. Please distinguish, if possible, requests for representation in misdemeanor cases from those for more serious crimes.

b. Please indicate (by percentage estimation, if possible) what the increase is over years prior to 2010, if any.

c. If no, please indicate whether you or your organization anticipate requests for representation in the future.

4. As a result of the IACAA, TLOA, and the 2013 VAWA, have you or your organization increased the number of representations in criminal cases in tribal courts?

a. If yes, please estimate the increase, if any, in the number of representations you or your organization have undertaken in criminal cases in tribal courts since 2010. Please distinguish, if possible, between representations in misdemeanor cases and those for more serious crimes. How does the number of criminal matters in tribal courts compare to the overall number of matters you or your organization has accepted since 2010?

b. If no, please indicate the number of matters you or your organization have undertaken in tribal courts since 2010.

5. As a result of the IACAA, TLOA, and the 2013 VAWA, have you or any staff attorney at your organization been appointed to represent a criminal defendant in tribal court proceedings?

a. If yes, please explain the court appointment process in the tribal court(s) in which the court appointment(s) took place.

b. Are you or your organization concerned about future court appointments in tribal courts? If yes, please indicate why.

6. Is there any additional information you would like to provide to LSC at this time about changes in tribal courts as a result of the TLOA and the 2013 VAWA that may have an impact upon you or your organization and its use of LSC funds?

III. Important Notes

Information received in response to this RFI may be published or summarized by LSC without acknowledgement of or permission by your organization. Furthermore, your responses may be releasable to the public under the LSC's adoption of the Freedom of Information Act, 42 U.S.C. 2996d(g), and the LSC regulation, 45 CFR part 1619. LSC, in its discretion, may request individual commenters to meet with LSC to elaborate on information in their written comments.

Comments sent by any method other than email to *lscrulemaking@lsc.gov,* or hard copy to Atitaya Rok, Staff Attorney, Legal Services Corporation, 3333 K St. NW., Washington, DC 20007; to any other address or individual, or received after the end of the comment period, may not be considered by LSC.

Dated: May 6, 2013.

Atitaya C. Rok,

Staff Attorney.

[FR Doc. 2013–11070 Filed 5–9–13; 8:45 am]

BILLING CODE 7050–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 13–867; MB Docket No. 13–102; RM–11696]

Radio Broadcasting Services; Moran, Texas

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document the Commission requests comment on a petition filed by Katherine Pyeatt (''Petitioner''), proposing to amend the FM Table of Allotments by allotting Channel 281A as a first local aural service at Moran, Texas. Channel 281A can be allotted at Moran, Texas, in compliance with the Commission's minimum distance separation requirements at the following reference coordinates: 32–25–00 NL and 99–08–00 WL. *See* Supplementary Information *infra.*

DATES: Comments must be filed on or before June 17, 2013 and reply comments must be filed on or before July 2, 2013.

ADDRESSES: You may submit comments, identified by MB Docket No 13–102, by any of the following methods:

- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *People with disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432

For detailed instructions for submitting comments and additional information of the rulemaking process, see the **SUPPLEMENTARY INFORMATION** sections of this document. In addition to filing comments with the FCC, interested parties should serve petitioner as follows: Katherine Pyeatt, 215 Cedar Springs Rd., #1605, Dallas, Texas 75201.

FOR FURTHER INFORMATION CONTACT: Deborah A. Dupont, Media Bureau (202) 418–7072.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MB Docket No. 13–XX, adopted April 24, 2013, and released April 26, 2013. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *www.bcpiweb.com.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506 (c)(4).

The Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications

Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Moran, Channel 281A.

[FR Doc. 2013–11124 Filed 5–9–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 383, 384 and 391

[Docket No. FMCSA–2012–0178]

RIN 2126–AB40

Medical Examiner's Certification Integration

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: FMCSA proposes to require certified medical examiners (MEs) performing physical examinations on drivers of commercial motor vehicles (CMV) to use a newly developed Medical Examination Report (MER) Form, MCSA–5875, in place of the current MER Form and to use Form MCSA–5876 for the medical examiner's certificate (MEC). In addition, MEs would be required to report results of all completed commercial drivers' physical examinations (including the results of examinations where the driver was found not to be qualified) to FMCSA by close of business on the day of the examination. This would include all CMV drivers who are required to be medically certified to operate in interstate commerce, not only those who hold or apply for commercial learner's permits (CLP) or commercial driver's licenses (CDL). Reporting of this information would be accomplished, by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via their individual password-protected National Registry web account. For holders of CDLs and CLPs, FMCSA also proposes to electronically transmit driver identification, examination results, and restriction information from the National Registry system to the State Driver Licensing Agencies (SDLAs). This includes those that have been voided by FMCSA because it finds that an ME has certified a driver who does not meet the physical certification standards. The Agency would also transmit medical variance information (exemptions, skills performance evaluation certificates and grandfathered exemptions) for all CMV drivers electronically to the SDLAs. Transmission of this information would allow authorized State and Federal enforcement officials to be able to view the most current and accurate information regarding the medical status of the CMV driver, all information on the MEC, and the medical variance information (as defined above) to include the issued and expiration dates.

DATES: Comments must be received on or before July 9, 2013.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2012–0178 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online 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., between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. Comments received after the comment closing date will be included in the docket, and we will consider late comments to the extent practicable. FMCSA may, however, issue a final rule at any time after the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Elaine Papp, Office of Medical Programs, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, by telephone at (202) 366–4001 or via email at *fmcsamedical@dot.gov.* Office hours are from 9 a.m. to 5 p.m. ET, Monday through Friday, except Federal holidays. If you have questions on viewing or submitting material to the docket, contact Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Request for Comments

FMCSA encourages you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you provide.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (FMCSA–2012–0178), 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 FMCSA can contact you if there are questions regarding your submission. To submit your comment online, go to *http://www.regulations.gov* and click on the ''Submit a Comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop-down menu, select ''Proposed Rules,'' insert ''FMCSA 2011–0178'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Submit a Comment'' in the ''Actions'' column. 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 your 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 the proposed rule based on your comments.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble, available in the docket, go to *http://www.regulations.gov* and click on the ''Read Comments'' box in the upper right-hand side of the screen. Then in the ''Keyword'' box, insert ''FMCSA–2012–0178'' and click ''Search.'' Next, click the ''Open Docket Folder'' in the ''Actions'' column. Finally, in the ''Title'' column, click on the document you would like 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 Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

C. Privacy Act

Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://www.gpo.gov/fdsys/pkg/FR-2008-01-17/pdf/E8-785.pdf.*

II. Executive Summary

A. Purpose and Summary of the Major Provisions

FMCSA proposes to require certified MEs performing physical examinations on drivers of CMV to use a newly developed Medical Examination Report (MER) Form, MCSA–5875, in place of the current MER Form and to use the prescribed Form MCSA–5876 for the MEC. In addition, MEs would be required to report results of all completed commercial drivers' physical examinations (including the results of examinations where the driver was found not to be qualified) to FMCSA by close of business on the day of the examination. This would include all CMV drivers who are required to be medically certified to operate in interstate commerce, not only those who hold or apply for CLP or CDL. Reporting of this information would be accomplished, by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via their individual password-protected National Registry web account. For holders of CDLs and CLPs, FMCSA also proposes to electronically transmit driver identification, examination results, and restriction information from the National Registry system to the SDLAs. This includes those that have been voided by FMCSA because it finds that an ME has certified a driver who does not meet the physical certification standards. The Agency would also transmit medical variance information (exemptions, skills performance evaluation certificates and grandfathered exemptions) for all CMV drivers electronically to the SDLAs. Transmission of this information would allow authorized State and Federal enforcement officials to be able to view the most current and accurate information regarding the medical status of the CMV driver, all information on the MEC, and the medical variance information (as defined above) to include the issued and expiration dates.

B. Benefits and Costs

The estimated economic costs of this proposed rule would not exceed the $100 million annual threshold, to be determined ''economically significant.'' The only additional cost imposed by the NPRM, would result from the ME entering the CMV Driver Medical Examination Results (MCSA–5850) data more frequently into the National Registry system. This cost is considered minimal in the amount of $455,994, as detailed in the Medical Qualifications Requirements Supporting Statement (OMB control number 2126–0006).

The potential estimated benefits are detailed in the table below. The revised OMB control numbers 2126–0006 and 2126–0011 Supporting Statements detail all revisions associated with the reduced annual paperwork burden hours.

SUMMARY OF QUANTIFIED BENEFITS

	Million
Removal of the requirement for employers to verify the MEs National Registry number for CDL drivers	$4.22
MEC and variance info sent electronically to SDLAs	2.17
SDLAs not recording MEC information	3.69
Total	10.1

The qualitative safety benefits of this rule are difficult to fully quantify. However, the Agency believes that the fraud prevention in electronic transmission of the MEC and variance information will continue to improve safety on public roads. In addition, physical qualification standards described in 49 CFR 391.41(b) will be more accurately determined for CMV drivers. The new MER Form, MCSA–5875, eliminates the advisory criteria (guidance) contained in the current MER Form that has been sometimes misinterpreted when applying the regulatory standards. Thus, MEs can make more accurate decisions regarding the physical qualification of CMV drivers.

III. Abbreviations

APN Advanced Practice Nurses
BLS Bureau of Labor Statistics
CAA Clean Air Act
CE Categorical Exclusion
CDL Commercial Driver's License
CDLIS Commercial Driver's License Information System
CLP Commercial Leaner's Permit
CMV Commercial Motor Vehicle
DC Doctors of Chiropractic
DO Doctor of Osteopathy
DOT U.S. Department of Transportation
DQ Driver Qualification
E-MAIL Electronic Mail
FHWA Federal Highway Administration
FMCSA Federal Motor Carrier Safety Administration
FMCSRs Federal Motor Carrier Safety Regulations
IC Information Collection
ICC Interstate Commerce Commission
IRFA Initial Regulatory Flexibility Analysis
MAP–21 Moving Ahead for Progress in the 21st Century Act
MD Medical Doctor
ME Certified Medical Examiner
MEC Medical Examiner's Certificate

MER Medical Examiner Report
MCSIA Motor Carrier Safety Improvement Act
MVR Motor Vehicle Record
NLETS National Law Enforcement Telecommunication System
NPRM Notice of Proposed Rulemaking
NRCME National Registry of Certified Medical Examiners
NTSB National Transportation Safety Board
OMB Office of Management and Budget
PA Physician Assistant
PIA Privacy Impact Assessment
PII Personally Identifiable Information
PRA Paper Reduction Act
RFA Regulatory Flexibility Act
SAFETEA–LU Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users
SDLA State Driver's Licensing Agencies
SPE Skill Performance Evaluation

IV. Legal Basis for the Rulemaking

The purpose of the principal requirements proposed in this NPRM is to modify the requirements adopted in two earlier final rules issued by FMCSA 73 FR 73096 (Dec. 1, 2008) and 77 FR 24104 (April 20, 2012) so that the information from the MEC transmitted to FMCSA, by close of business on the day of the examination by MEs for drivers required to have a CDL, would then be promptly and accurately transmitted to the SDLAs electronically for entry into the appropriate CDL driver record within one business day of receipt from FMCSA. In view of this purpose, the legal bases of the two previous final rules also serve as the legal basis for this proposed rule. The primary legal basis for the 2008 final rule, Medical Certification Requirements as Part of the Commercial Driver's License, is section 215 of Motor Carrier Safety Improvement Act (MCSIA) [Pub. L. 106–159, 113 Stat. 1767 (Dec. 9, 1999)] (set out as a note to 49 U.S.C. 31305). The primary legal basis for the 2012 final rule, National Registry of Certified Medical Examiners, is 49 U.S.C. 31149, enacted by section 4116(a) of Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, Public Law 109–59, 119 Stat. 1726 (Aug. 10, 2005) (SAFETEA–LU). Brief summaries of the relevant legal bases for the proposed requirements in this NPRM are set out below. More detailed discussions of the legal basis for each of the previous final rules published in 2008 and 2012 may be found in their preambles, at 73 FR 73096–73097 and 77 FR 24105–24106, respectively.

A. Authority Over Drivers Affected

1. Drivers Required to Obtain a MEC

FMCSA is required by statute to establish standards for the physical qualifications of drivers who operate CMVs in interstate commerce for non-excepted industries. [49 U.S.C. 31136(a)(3) and 31502(b)].

Subject to certain limited industry exceptions,[1] FMCSA has fulfilled the statutory mandate of 49 U.S.C. 31136(a)(3) by establishing physical qualification standards for all drivers covered by these provisions. [49 CFR 391.11(b)(4)]. Such drivers must obtain from a ME a certification indicating that the driver is physically qualified to drive a CMV. [49 CFR 391.41(a), 391.43(g) and (h)]. Sec. 32911 of the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141, 126 Stat. 405, July 6, 2012) recently added an additional requirement to ensure that ''an operator of a CMV is not coerced by a motor carrier, shipper, receiver, or transportation intermediary to operate a CMV in violation of a regulation promulgated under this section, or chapter 51 or chapter 313 of this title'' [49 U.S.C. 31136(a)(5)]. See the discussion in the Proposed Rule Section below. FMCSA is also required to consider, to the extent practicable and consistent with the purposes of the statute, costs and benefits of the rule. 49 U.S.C. 31136(c)(2)(A).

2. Drivers Required to Obtain a CDL

The authority for FMCSA to require an operator of a CMV to obtain a CDL rests on the authority found in 49 U.S.C. 31302.

B. Authority to Regulate State CDL Programs

FMCSA, in accordance with 49 U.S.C. 31311 and 31314, has authority to prescribe procedures and requirements for the States to observe in order to issue CDLs. [see, generally, 49 CFR Part 384]. In particular, under section 31314, in order to avoid loss of funds apportioned from the highway trust fund, each State shall comply with the following requirement:

> (1) The State shall adopt and carry out a program for testing and ensuring the fitness of individuals to operate commercial motor vehicles consistent with the minimum standards prescribed by [FMCSA] under section 31305(a) of [Title 49 U.S.C.].

49 U.S.C. 31311(a)(1). *See also* 49 CFR 384.201.

C. Authority To Require Reporting by MEs

FMCSA has authority under 49 U.S.C. 31133(a)(8) and 31149(c)(1)(E) to require MEs on the National Registry to record and retain the results of the physical examinations of CMV drivers and to require frequent reporting of the information contained on all of the MECs they issue. Section 31133(a)(8) gives the Agency broad administrative powers (specifically ''to prescribe recordkeeping and reporting requirements'') to assist in ensuring motor carrier safety. [Sen. Report No. 98–424 at 9 (May 2, 1984)]. Section 31149(c)(1)(E) authorizes a requirement for electronic reporting of certain specific information by MEs, including applicant names and numerical identifiers as determined by the FMCSA Administrator. Section 31149(c)(1)(E) sets minimum monthly reporting requirements for MEs and does not preclude the exercise by the Agency of its broad authority under § 31133(a)(8) to require more frequent and more inclusive reports.[2] In addition to the general rulemaking authority in 49 U.S.C. 31136(a), the Secretary of Transportation is specifically authorized by section 31149(e) to ''issue such regulations as may be necessary to carry out this section.''

Authority to implement these various statutory provisions has been delegated to the Administrator of FMCSA [49 CFR 1.87(f)].

V. Background

As stated in the Legal Basis section, this NPRM is a follow-on rule to both the National Registry of Certified Medical Examiners (NRCME) published on April 20, 2012 (77 FR 2410) and the Medical Certification Requirements as Part of the CDL rule (Med-Cert rule) published on December 1, 2008 (73 FR 73096). It would also be the third rule of an initiative to improve the driver qualification and medical examiner's certificate process. A summary of the major relevant provisions of those two final rules, outlined in V A and V B, provides the background for the proposed rulemaking. In addition, the Agency is also proposing substantial revisions to the MER Form and related regulatory provisions. A summary of the development of that report is also set forth below in V C.

A. Medical Certification Requirements as Part of the CDL

FMCSA's 2008 final rule, Medical Certification Requirements as Part of the Commercial Driver's License [73 FR 73096 (Dec. 1, 2008)] adopted a number of regulatory provisions designed to incorporate information from the MEC into the Commercial Driver's License Information System (CDLIS).

[1] *See* 49 CFR 390.3(f) and 391.2.

[2] The provisions of § 31149(c)(1)(E) have been amended by § 32302(c)(1)(A) of Moving Ahead for Progress in the 21st Century, Public Law 112–141, 126 Stat. 405 (July 6, 2012) (''MAP–21'').

Subsequent actions of the Agency modified some of the provisions adopted in the 2008 final rule [see Medical Certification Requirements as Part of the Commercial Driver's License (CDL); Technical, Organizational, and Conforming Amendments, 75 FR 28499 (May 21, 2010) and Medical Certification Requirements as Part of the Commercial Driver's License (CDL), Extension of Certificate Retention Requirements, 76 FR 70661 (Nov. 15, 2011)]. Most of the requirements established by these actions took effect on January 30, 2012. But some requirements affecting CDL drivers and their employers will not take effect until January 30, 2014.

In addition, FMCSA established new uniform requirements for CLPs in the final rule published May 9, 2011, Commercial Driver's License Testing and Commercial Learner's Permit Standards [76 FR 26854]. As a result, the medical certification requirements of the 2008 final rule will apply to applicants and holders of CLPs beginning on July 8, 2014. As modified by these actions, the essential elements of these CDL and CLP medical certification provisions for each of the affected groups are summarized below:

1. SDLAs

The Medical Certification Requirements as Part of the Commercial Driver's License Rule requires the States to modify their CDL procedures to: (1) Record a CDL or CLP driver's self-certification regarding type of driving (*e.g.,* interstate (non-excepted or excepted) and intrastate (non-excepted or excepted) on the CDLIS driver record); (2) require submission of the original or copy of the MECs from drivers operating in non-excepted, interstate commerce who are required by 49 CFR Part 391 to be medically certified; (3) retain the certificate or a copy for 3 years from the date of issuance; (4) post the required information from the certificate or a copy onto the CDLIS driver record within 10 calendar days; (5) update the medical certification status of the CDLIS driver record to show the driver as ''not-certified'' if the certification expires; and (6) downgrade the CDL or CLP within 60 days of the expiration of the driver's MEC. There are also requirements for posting certain information about any medical variances (as defined in the SUMMARY section) issued to the driver on the CDLIS driver record.

If the driver certifies that he or she expects to drive in interstate commerce and is not driving exclusively for one of the industries excepted from the requirements of 49 CFR part 391, the Medical Certification Requirements as Part of the Commercial Driver's License Rule requires the State to post within 10 calendar days on the CDLIS driver record the following information from that driver's MEC: (1) ME's name; (2) ME's license or certificate number and the State that issued it; (3) expiration date of the MEC; (4) ME's telephone number; (5) date of physical examination/issuance of the MEC to the driver; (6) National Registry identification number for the ME; (7) medical certification status determination (i.e., ''certified'' or ''not certified''); (8) existence of any medical variance (as defined in the SUMMARY section) on the medical certificate (9) any driver restrictions; and (10) the date the information is entered on the CDLIS driver record.

In addition to the recordkeeping functions, the SDLA must make the driver's medical certification status information electronically accessible to authorized State and Federal enforcement officials via CDLIS and the National Law Enforcement Telecommunication System (NLETS), and to drivers and employers via CDLIS motor vehicle records (MVRs). Based on the Medical Certification Requirements as Part of the Commercial Driver's License Rule, authorized State and Federal enforcement officials will be able to view the most current and accurate information regarding the medical status of the CMV driver, all information on the MEC, and the medical variance information (as defined above) to include the issued and expiration dates.

2. Motor Carriers and Employers

Motor carriers who employ a CDL driver to operate in non-excepted, interstate commerce must place the driver's current CDLIS MVR documenting the driver's medical certification status in the driver's qualification (DQ) file before allowing the driver to operate a CMV. The MEC that the driver provided to the SDLA may be used for this purpose for up to 15 days from the date the certificate was issued by the ME. The motor carrier must obtain the CDLIS MVR to verify: (1) The driver's self-certification to operate in non-excepted, interstate commerce; (2) that a non-excepted, interstate driver has a medical certification status of ''certified;'' and, if applicable (3) documentation that the driver was issued a medical variance (as defined in the SUMMARY section) by FMCSA. After the 15th day, the carrier must have obtained a copy of the CDLIS MVR as documentation that the driver is medically ''certified'' and retain the MVR in the DQ file. This record must be checked annually.

3. Drivers

All interstate CDL holders subject to the physical qualifications standards of 49 CFR part 391 must meet the following requirements:

- Beginning January 30, 2012, all drivers applying for an initial, renewal, upgrade or transfer of a CDL must provide the MEC to the SDLA, and update that information whenever a new certificate is issued.
- Beginning January 30, 2012 but not later than January 30, 2014, all existing CDL holders who do not have a renewal, upgrade or transfer issuance must still provide the MEC to the SDLA. Thereafter, they must update that information with the SDLA whenever a new certificate is issued.
- Beginning on January 30, 2014, these drivers will no longer have to use the MEC as proof of his or her certification to enforcement personnel or employers, except for the first 15 days after issuance,
- Beginning on January 30, 2014, these drivers will no longer be allowed to carry the actual MEC after the first 15 days after issuance, but must continue to carry any SPE certificate or medical exemption document while on duty.
- Beginning on July 8, 2014, the above requirements will also apply to CLP holders.

Non-CDL holders, subject to the physical qualifications standards of 49 CFR Part 391 will continue to be required to carry the original or a copy of the MEC and any SPE certificate or medical exemption document while on duty.

B. National Registry of Certified MEs

In 2012, FMCSA issued a final rule establishing the National Registry of Certified Medical Examiners (NRCME) [77 FR 24104 (Apr. 20, 2012]. This rule established training and testing requirements for medical professionals who conduct the medical certification examinations of interstate CMV drivers. Current regulations require all interstate commercial drivers (with certain limited exceptions) to be medically examined by an ME (as defined in 49 CFR. 390.5) to determine if these drivers meet FMCSA's physical qualification requirements. The MEs who conduct such physical examinations must retain copies of the MER Forms of all drivers they examine and certify. The MER Form lists the specific results of the various medical tests and assessments used to determine if a driver meets the physical qualification standards set

forth in subpart E of part 391 of the FMCSRs.

The NRCME rule established the National Registry to ensure that all MEs who conduct driver medical examinations have been trained on FMCSA physical qualifications standards and guidelines. In order to be listed on the National Registry, MEs are required to participate in a training program from an accredited provider and pass a certification test to assess their knowledge of the Agency's physical qualifications standards and guidelines and how to apply them to commercial drivers. Upon passing this certification test, and meeting the other administrative requirements associated with the program, MEs will be listed on the National Registry. Once the full compliance date of May 21, 2014 is reached, the Agency will only consider MECs issued to commercial drivers by MEs on the National Registry as valid proof of medical certification. The National Registry final rule also addressed several of the recommendations from National Transportation Safety Board (NTSB) for FMCSA to consider in order to improve the performance of MEs and to ensure that CMV drivers meet the physical qualification standards of the FMCSRs.[3]

One of the administrative requirements for being listed on the National Registry is for the ME to submit a CMV Driver Medical Examination Results Form, MCSA–5850, to FMCSA for every physical examination conducted on both CDL and non-CDL drivers. Beginning on May 21, 2014, the NRCME rule will require MEs to submit this information monthly. The CMV Driver Medical Examination Results Form, MCSA–5850, will include almost all of the information on the MEC. The information not included on the form includes the ME's name, address, healthcare profession, state licensing number, state issued by identifier, national registry number and the date the MEC was signed. The information listed is not on the form because it is captured by the National Registry system upon the ME signing in via their individual password-protected National Registry web account. The information from the CMV Driver Medical Examination Results Form, MCSA–5850, and the information captured by the National Registry system upon the ME signing in via their individual password-protected National Registry web account will be combined and forwarded from the National Registry system to the SDLAs to account for all of the information on the MEC.

C. MER

The current version of the MER Form, and the instructions and requirements for its use, have evolved over a number of years. The form and the instructions are presently found in the FMCSRs at 49 CFR 391.43(f). Between 1940 and 1952, the regulations adopted by one of FMCSA's predecessor agencies, the Interstate Commerce Commission (ICC), included a ''Standard Physical Examination Form'' and accompanying instructions for use by doctors of medicine (the only medical practitioners then allowed to perform such examinations), but its use was recommended and not compulsory [former 49 CFR 191.4 (1951 ed.)]. In 1952, the ICC revised the form and the instructions, and revised the regulations to require that the MEC ''be based on a physical examination made and recorded generally in accordance with the following instructions and examination form'' The MER Form and instructions were largely unchanged [*Qualifications of Employees and Safety of Operations,* 54 M.C.C. 337 (1952) and former 49 CFR 191.11 (1952 ed.), 17 FR 4423, 4425–26 (May 15, 1952)].

The regulations issued by the ICC regarding motor carrier safety were adopted by DOT after the transfer of responsibility from the ICC, by Public Law 89–670, 80 Stat. 931 (Oct. 15, 1966), and were renumbered twice without substantive change [32 FR 17941 (Dec. 15, 1967) and 33 FR 19729–32 (Dec. 25, 1968)]. In 1970, the Federal Highway Administration (FHWA), made the first significant revisions in both the examination form and the instructions, which were then, as now, included in 49 CFR. 391.43 [Qualifications of Drivers, 35 FR 6458 (Apr. 22, 1970)]. Over the next 30 years, a number of changes were made, largely as conforming changes to reflect revisions in the physical qualification standards or the rules for controlled substance testing.

In 2000, FMCSA issued a final rule adopting both significant revisions to the instructions and a completely revised MER Form, both of which were substantially in the form in which they appear today in 49 CFR 391.43(f). The purpose of the revisions was to organize the form to: ''(1) gain simplicity and efficiency; (2) reflect current medical terminology and examination components; and (3) be a self-contained document (i.e., the form will, to the extent possible, include all relevant information necessary to conduct the physical examination and certification).'' [Physical Qualification of Drivers; Medical Examination; Certificate, 65 FR 59363 (Oct. 5, 2000)]. The report was expanded to include a recitation of the physical qualification standards and to provide space to allow recording of laboratory and test data. The MER Form also included a number of advisory criteria providing guidelines from the Agency to assist MEs assess a driver's physical qualifications. FMCSA noted that ''These guidelines are strictly advisory and were established after consultation with physicians, States and industry representatives.'' (65 FR 59364). Since the 2000 revision, the MER Form and the instructions have been revised to reflect changes in the standards or advisory guidelines relating to hypertension and use of Schedule I drugs [Motor Carrier Safety Regulations; Miscellaneous Technical Amendments, 68 FR 56199 (Sep. 30, 2003) and Harmonizing Schedule I Drug Requirements, 77 FR 4479 (Jan. 30, 2012) and 77 FR 10391 (Feb. 22, 2012)].

VI. Discussion of Proposed Rule

This NPRM is a follow-on rule to both the National Registry of Certified Medical Examiners published on April 20, 2012 (77 FR 2410) and the Medical Certification Requirements as Part of the CDL rule (Med-Cert rule) published on December 1, 2008 (73 FR 73096). It would also be the third component of an initiative to improve the driver qualification and medical examiner's certificate process.

A. Overview

FMCSA proposes that MEs be required to report the results of all completed commercial drivers' physical examinations to FMCSA by close of business on the day the examination is conducted, by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via their individual password-protected National Registry web account. The report would include the results of examinations where the driver was found to be qualified, not qualified and where the ME would indicate that the determination was pending. When the driver was determined to be not qualified, all previous certificates issued to the driver would be deemed invalid. FMCSA would then transmit all of the information from the MEC electronically from the National Registry system to the SDLAs for CLP and CDL holders only. FMCSA anticipates delivering the information to the SDLA the next business day after receipt. It also proposes to transmit to the SDLAs

[3] See NTSB Safety Recommendations H–01–17 through H–01–25, *http://www.ntsb.gov/doclib/recletters/2001/H01_17_25.pdf* (retrieved Feb. 21, 2012).

information about MECs for CDL and CLP drivers that have been invalidated because a subsequent examination has found that the driver is not physically qualified. The SDLAs would then record the driver's status on the CDLIS driver record as ''not certified'' and begin the process of downgrading the CDL in accordance with existing procedures. In addition, the Agency would transmit medical variance information (as defined in the **SUMMARY** section) for all interstate CMV drivers electronically to the SDLAs.

For interstate CMV drivers required to have CDLs or CLPs (after July 8, 2014), FMCSA would then be able to promptly transmit to the SDLAs the drivers' MEC information for entry on the State-managed CDL driver records. For physically qualified non-CDL drivers, the ME will continue to issue a paper MEC, Form MCSA–5876. The ME has the option to either fill in the MEC by hand or to generate an electronically populated copy if the examination information is submitted to the National Registry system at the time of the examination.

FMCSA proposes that the MEs allow and encourage all drivers to review their information on the CMV Driver Medical Examination Results Form, MCSA–5850. This review would reduce data entry errors that will be transmitted to the National Registry and then to the States potentially hindering delivery of the medical certification information to the intended CDLIS driver record.

The medical variance information would originate with FMCSA. A medical variance (as defined in the **SUMMARY** section) is issued by FMCSA to a driver who would otherwise not meet the physical qualification standards in 49 CFR 391.41(b). See proposed 49 CFR 383.73(o)(1)(i)(B)(8), and (o)(2) and (3). FMCSA would transmit this medical variance information for all CMV (both CDL and non-CDL) drivers electronically to the appropriate SDLAs whenever FMCSA issues, renews, or rescinds a medical variance. FMCSA proposes to require the SDLAs to update CDLIS driver records each business day with medical variance information (as defined in the **SUMMARY** section) transmitted from FMCSA for CLP and CDL drivers. This will allow the most current information about the medical status of CDL drivers to be made available promptly and accurately.

FMCSA will also forward information to the SDLAs when FMCSA voids a MEC issued to a driver required to have a CDL or CLP. Under the authority granted by 49 U.S.C. 31149(c)(2), FMCSA may void a MEC issued to a CMV driver if it finds either that an ME has issued a certificate to a driver ''who fails to meet the applicable standards at the time of the examination'' or ''that a medical examiner has falsely claimed to have completed training in physical and medical examination standards.'' Some examples of circumstances in which the driver does not meet the applicable standards that might trigger such action by the Agency could include, but would not be limited to, when a driver has falsified or omitted disclosing potentially disqualifying medical information to the ME at the time of the examination or when a ME has not applied correctly the physical qualification standards in deciding that the driver was physically qualified. The Agency is developing internal processes for evaluating the validity of certificates in the wide variety of possible situations where such review appears to be appropriate under the statutory standard. This will include review of the data submitted by MEs to the National Registry system, as well as complaints, field investigations, crash reports and other sources.

Before voiding the MEC, FMCSA will provide the affected driver a notice of the proposed action and an opportunity either to obtain a new MEC, if appropriate, or to provide the Agency with any legal or factual reasons why the action should not be taken. If the decision is made to void the driver's certificate, FMCSA would notify the driver. If the driver holds a CDL or CLP, notification would be transmitted by FMCSA to the driver's SDLA through the National Registry, and the SDLA would change the CDL or CLP driver's medical status to ''not certified'' and notify the driver of the action taken.

B. Medical Examination Procedures

FMCSA proposes to remove the Instructions for Performing and Recording Physical Examinations from 49 CFR 391.43(f), because FMCSA recognizes that MEs, who have been licensed, certified, or registered in accordance with applicable State laws and regulations to perform physical examinations thereby possess the knowledge, skills, and abilities to perform physical examinations, and do not need general instructions in performing and recording physical examinations. New versions of the Instructions for Performing and Recording Physical Examinations will be published in FMCSA guidance documents.

FMCSA also proposes to require MEs to begin using a newly developed MER Form, MCSA–5875, in place of the current MER Form. This form was developed by FMCSA in consultation with health care practitioners that are familiar with performing driver medical examinations. The use of the proposed form would be required, and is being submitted for the necessary approvals under the Paperwork Reduction Act, 44 U.S.C. 3501–21. The proposed MER Form, MCSA–5875, would make the information collected on driver health history more comprehensive, streamline the format, strengthen the efficiency of frequently used clinical processes and tools for performing driver physical examinations, expand the ME determination section, add a statement for the ME signature, add a National Registry Number, and add a section for amending the ME determination.

The revised MER Form, MCSA–5875, would no longer include information about the driver's role, a listing of physical qualification standards for drivers, detailed instructions for performing the examination, and the medical advisory criteria. Information about the driver's role, detailed guidance about performing the examination, and the medical advisory criteria would be published in FMCSA guidance documents. The physical qualification standards are published in the FMCSRs. Both will be covered in training required for an ME to be listed on the National Registry.

The MER Form, MCSA–5875, would expand the ME determination section by eliminating the ''Temporarily Disqualified'' option and adding a ''Pending Determination'' option to defer a decision temporarily for up to 45 days, if the ME requires additional information to make a determination of whether or not the driver was qualified. The form would also add a place for an ME to amend the certification decision if the driver did not require a completely new examination. FMCSA would consider any CMV Driver Medical Examination Results Form, MCSA–5850, displaying a ''Pending Determination'' status as an incomplete examination. This information will be submitted and stored only in the National Registry system. If the disposition of the pending examination is not updated by the ME before the 45 day expiration date, FMCSA would notify the ME and the driver in writing that the examination is no longer valid and that the driver is required to be re-examined. FMCSA will retain the invalidated examination information in the National Registry System.

C. SDLAs

SDLAs would no longer require CLP and CDL holders and applicants to provide their MECs or accept medical

variance documents (as defined in the **SUMMARY** section) from CLP and CDL drivers required to have a medical variance. The SDLA would receive information about CDL and CLP drivers determined to be physically qualified electronically from FMCSA, as well as information about drivers whose MECs have been invalidated because the driver has been determined to be not physically qualified as a result of a subsequent examination. The SDLAs would be required to update CLP and CDL driver records with medical certification information within one business day of receipt from FMCSA. In addition, the SDLAs would be required to update driver medical variance information (for CDL and CLP drivers) within one business day of receipt from FMCSA.

D. Drivers

Drivers who are required to have a CDL or a CLP would no longer be required to provide either their MECs or any medical variance documents (as defined in the **SUMMARY** section) to the SDLA. FMCSA would provide that information to the SDLA electronically. CDL or CLP drivers would no longer be required to carry a valid MEC while operating a CMV, even during the first 15 days after it is issued because the MEC information would be electronically transmitted from the ME to the National Registry system by close of business on the day of the examination. FMCSA would then promptly transmit the information from the National Registry system to the SDLAs electronically for entry into the appropriate CDL driver record. The MEC information would be posted to the driver's record, by the SDLA, within one business day of receiving the information from FMCSA. The electronic record of the driver's medical certification would be the only valid evidence that the driver was physically qualified. Non-CDL drivers will continue to be required to carry the original, or a copy, of the MEC. All CMV drivers would however be required to carry any relevant medical variance documents (as defined in the **SUMMARY** section).

FMCSA does not believe this proposed rule would result in any operator of a CMV being coerced to violate any other safety regulations, because the proposed rule is entirely designed to enhance compliance with the physical qualification requirements applicable to all CMV drivers. Indeed, by providing MEC information and medical variance information (as defined in the **SUMMARY** section) directly to the SDLAs, FMCSA will eliminate the opportunity for drivers to provide fraudulent documents to their SDLAs and the opportunity for motor carriers, shippers, receivers, or transportation intermediaries to coerce them to do so. In addition, CDL MEC information will be transmitted to the SDLAs only for drivers certified by an ME listed on the National Registry, thereby eliminating the possibility of motor carriers coercing drivers to operate without a valid MEC.

E. MEs

MEs would complete the new MER Form, MCSA 5875, when performing driver physical examinations, based on FMCSA regulations and advisory criteria published by FMCSA. They would be required to report results of all driver physical examinations, including those who failed to meet the FMCSA physical qualification standards and those who are pending further evaluation before the physical qualification determination is made, to FMCSA by close of business the same day by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via their individual password-protected National Registry web account. MEs would allow and encourage all drivers to review their information on the CMV Driver Medical Examination Results Form, MCSA–5850 to ensure the driver's personal information (name, address, driver's license number, etc.) are correct. The prompt and complete reporting to FMCSA by the MEs of the medical certification information will enable this information (for CMV drivers required to have a CDL or CLP) to be transmitted expeditiously to the SDLAs for posting on the CDLIS driver record for the driver involved. This will ensure that complete, up-to-date and accurate information about the medical certification status of such drivers is available to State and federal enforcement personnel, SDLAs, employers, drivers and others who rely on this information to ascertain whether a driver is in compliance with the applicable physical qualification standards and is able to operate a CMV safely. If the ME determined the non-CDL driver was physically qualified, they would complete the MEC, Form MCSA–5876, obtain the driver's signature, and provide the certificate to the driver (and a copy to the employer, if requested to do so).

In addition, FMCSA proposes to require all MEs to notify FMCSA if they have not performed any driver physical examinations during the previous month. The compliance date for this provision would coincide with the effective date of the final rule to enable FMCSA to monitor ME compliance with reporting requirements.

F. Motor Carriers

Motor carriers would no longer be required to verify the National Registry Number of the ME who issued a MEC to a driver required to have a CDL or a CLP by accessing the public information available on the National Registry. All certification information for such drivers would be provided to the SDLAs and posted as part of the driver record only by MEs listed on the National Registry. Motor carriers would still be required to obtain each driver's driver record from the SDLA which licensed the driver. The motor carrier would verify that the driver's status is ''medically certified'' and that the driver has the documentation for all medical variances (as defined in the **SUMMARY** section) noted on the MEC. For any CMV drivers who are not required to have a CDL, motor carriers would still have to verify that the ME was listed on the National Registry.

For drivers required to have a CDL or a CLP, motor carriers would no longer be permitted to rely on an original or copy of a MEC in the DQ file for the first 15 days after it is issued. The motor carrier would obtain the driver's medical information as part of the CDLIS MVR from the SDLA.

G. Implementation Date

In order to allow sufficient time for the SDLAs and FMCSA to develop and implement the necessary changes in their information systems to accomplish the proposed changes, FMCSA proposes to require that most of the proposed rules would take effect three years after the effective date of the final rule. The provisions requiring: (1) MEs to notify FMCSA if they have not performed any driver physical examinations during the previous month; (2) MEs to use the new MER Form, MCSA–5875; (3) the State to post the medical variance information (as defined in the SUMMARY section) provided by FMCSA, including the dates of issuance and expiration, to the CDLIS driver record within 1 business day of receipt for CLP and CDL drivers; (4) the State to update the medical status to ''not certified' when the medical certification is voided by FMCSA; and (5) MEs to use the prescribed form for the MEC would go into effect on the effective date of the final rule.

FMCSA proposes that beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], MEs be required to report the results of all commercial drivers' physical examinations to FMCSA by

close of business on the day the examination is conducted (instead of once a month), by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via their individual password-protected National Registry web account. FMCSA would then transmit all of the information from the MEC electronically from the National Registry system to the SDLAs for CLP and CDL holders only. FMCSA is proposing this date based on its estimate of when all States will have the information technology systems in place to receive the information from the National Registry. However, if the Agency finds that the States are ready earlier than expected the Agency may decide to shorten the proposed period and make this requirement before three years after the effective date.

VII. Section-by-Section

This section includes a summary of the regulatory changes proposed for 49 CFR parts 383, 384 and 391 organized by section number.

A. Proposed Changes to Part 383

Part 383 contains the requirements for CLPs and CDLs. With certain exceptions, the rules in this part apply to every person who operates a CMV in interstate, foreign or intrastate commerce, to all employers of such persons, and to all States.

Section 383.71(h). FMCSA proposes to change the requirement of a CLP or CDL applicant or holder who is required to obtain a MEC (no number assigned) from providing the State with an original or copy of the MEC (no number assigned) to FMCSA providing the State with the electronic MEC information.

Section 383.73(a)–(b). FMCSA proposes to change the requirement that the State must post the MEC (no number assigned) received from the CLP or CDL applicant or holder to the CDLIS driver record to the State posting the electronic MEC information received from FMCSA.

Section 383.73(o). FMCSA proposes to change the State requirement of posting the original or copy of the MEC (no number assigned) information to the CDLIS driver record within 10 calendar days after receipt to the posting of the electronic MEC, Form MCSA–5876, information to the CDLIS driver record within 1 business day after receiving the electronic information from FMCSA. The proposal would also add a requirement that, when the SDLA receives information that a driver's MEC has been invalidated because the driver has been found to be not physically qualified in a subsequent examination by an ME on the National Registry, it must change the driver's status on the CDLIS record to ''not certified'' and begin the process for downgrading the CDL or CLP. FMCSA also proposes to change the requirement that the State retain an original or copy of the MEC (no number assigned) for 3 years to a requirement that it retain an electronic record of the MEC, Form MCSA–5876, information for 3 years.

While the American Association of Motor Vehicle Administration's ''Commercial Driver's License Information System State Procedures Manual,'' Release 5.2.0, February 2011 requires the State to post the medical variance information (as defined in the **SUMMARY** section) provided by FMCSA, including the dates of issuance and expiration, and was previously incorporated by reference in § 384.105 of this chapter, FMCSA proposes to also include this requirement in paragraph (o) along with the MEC, Form MCSA–5876, information posting requirement as a reminder to the States. This proposed requirement would be effective immediately because States are already required to post this information. FMCSA also proposes to reduce the time the State has to post the medical variance information (as defined in the **SUMMARY** section) received from FMCSA to the CDLIS driver record from within 10 calendar days to 1 business day of receipt since the information will be sent electronically.

FMCSA proposes a new requirement that the State must also update the medical status to ''not certified' when the medical certification is voided by FMCSA.

B. Proposed Changes to Part 384

Part 384 contains the requirements to ensure that the States comply with the provisions of section 12009(a) of the Commercial Motor Vehicle Safety Act of 1986 (49 U.S.C. 31311(a). Part 384 includes the minimum standards for the actions States must take to be in substantial compliance with each of the 22 requirements of 49 U.S.C. 31311(a), establishes procedures for FMCSA determinations of State compliance, and specifies the consequences of State noncompliance.

Section 384.234. FMCSA proposes an administrative amendment to this section to include driver medical certification recordkeeping requirements for CLP applicants in Part 383.

Section 384.301. FMCSA proposes to amend this section by adding a new paragraph (i). FMCSA has always given the States 3 years after the effective date of any new rule to come into substantial compliance with new CDL requirements. This allows the States time to pass any necessary new legislation and modify State systems to comply with the new requirements, including CDLIS. New paragraph (i) would specify the 3 year compliance date for States.

C. Proposed Changes to Part 391

Part 391 establishes minimum qualifications for persons who drive CMVs. The requirements in this part also establish minimum duties of motor carriers with respect to the qualifications of their drivers.

Section 391.23(m)(2)(i)(A). FMCSA proposes an editorial change to eliminate an erroneous reference to § 383.71(a)(1)(ii) and to add a reference to 383.71(b)(1)(ii), which describes the four types of self-certifications.

Section 391.23(m)(2)(i)(B). The rule would eliminate the requirement for the motor carrier to verify and document in the DQ file that a CDL driver was certified by an ME listed on the National Registry. Employers will no longer need to verify that the driver examination was performed by an ME listed on the National Registry by FMCSA, because that information will be sent to the SDLAs from the National Registry. Motor carriers will still be required to meet this requirement for non-CDL drivers.

Section 391.41(a)(2). 3 years after the effective date of the final rule, FMCSA proposes to eliminate the provision allowing drivers required to have a CDL or a CLP to carry a current MEC (no number assigned) for 15 days.

Section 391.43. FMCSA proposes eliminating the Instructions for Performing and Recording Physical Examinations section in § 391.43(f) to eliminate redundant or unnecessary requirements. The Instructions section contains information found elsewhere in FMCSA guidance and information that health care practitioners must be knowledgeable of in order to be licensed, registered or certified by their States to perform physical examinations. FMCSA proposes revising the MER Form in § 391.43(f) to make the driver's health history information more comprehensive, streamline the format, strengthen the efficiency of frequently used clinical processes and tools for performing driver physical examinations, expand the ME determination section, add a statement for ME signature, add a National Registry Number, and add a section for amending the ME determination.

FMCSA proposes in 391.43(g)(2) that, beginning 3 years after the effective date of the final rule, MEs would no longer

be required to provide the MEC, Form MCSA–5876, to drivers required to have a CDL or CLP (and their employers) because the MEC information would be promptly and accurately transmitted electronically to the SDLAs for entry on the CDLIS driver record. But the ME would still provide the MEC, Form MCSA–5876, to non-CDL drivers (and requesting employers), as currently required.

FMCSA proposes to insert two new paragraphs in 49 CFR 391.43(g). The first one, new paragraph (g)(3), would require the ME to inform the driver if a determination has been made that the driver is not physically qualified, and that this information will be reported to FMCSA. Upon receiving this report, FMCSA would then invalidate any MECs previously issued to the driver that are contained in the Agency's records. The second one would require the ME to inform the driver if the determination of whether the driver is physically qualified requires additional information or further examination. This pending status will remain in effect for 45 days, and will be reported to FMCSA. If the examination is not completed within the 45-day period, the examination will be no longer valid and the driver will be required to obtain a new examination in order to obtain a MEC, Form MCSA–5876.

FMCSA proposes in 391.43(g)(5)(A)(ii) (renumbered from (g)(3) because of the two new paragraphs proposed above) that, beginning 3 years after the effective date of the final rule, the ME must report results of all commercial drivers' physical examinations to FMCSA by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via the ME's individual password-protected National Registry web account by the close of the same business day. As indicated above, FMCSA may shorten this period if the States are ready before 3 years to begin receiving medical certification for drivers required to have a CDL or CLP.

FMCSA proposes in 391.43(g)(5)(B) to require MEs to report to FMCSA whenever the ME does not complete any driver medical examinations during the preceding 30 days, beginning on the effective date of the final rule.

FMCSA proposes to revise 391.43(h) to require MEs to use the MEC, Form MCSA–5876, and will seek approval under the Paperwork Reduction Act for its use. (See the Regulatory Analysis section below.) Only minor editorial edits have been made to the form for clarity. The information required to be entered on the certificate is unchanged from the information required under the current regulation.

Section 391.45. FMCSA proposes to add a new paragraph at the end of this section that would require a driver to be medically examined and certified before operating a CMV after previous certifications have been invalidated because of a driver not being physically qualified under the provisions of proposed new 391.43(g)(3).

Section 391.51. FMCSA proposes in 391.51(b)(7) to eliminate the exception that allows the motor carrier to use a MEC (no number assigned) as proof of medical certification in the DQ file, because States would be required to load medical certification information into the driver's record within one business day of receipt from FMCSA.

VIII. Regulatory Analyses

A. E.O. 12866 (Regulatory Planning and Review and DOT Regulatory Policies and Procedures as Supplemented by E.O. 13563)

FMCSA has determined this proposed rule is not a significant regulatory action within the meaning of Executive Order (E.O.) 12866, as supplemented by E.O. 13563 (76 FR 3821, January 21, 2011), and is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980; 44 FR 11034, February 26, 1979) because it is not expected to generate substantial congressional or public interest. The estimated cost of the proposed rule is not expected to exceed the $100 million annual threshold for economic significance. The Agency expects this proposed rule to generate net cost savings because of reduced annual paperwork burden hours compared to the current information collection activity (IC). The motor carriers and SDLAs affected will benefit from a decrease in annual burden hours and economic expenditures that will more than offset the burden increase for MEs.

FMCSA proposes to transmit MEC information electronically from the National Registry system to the SDLAs for CLP and CDL drivers. The Agency will also transmit medical variance information (as defined in the **SUMMARY** section) for all CMV drivers electronically to the SDLAs.

The MEC information would originate with the ME. The ME would perform a driver physical examination and record the results on a MER Form, MCSA–5875. The ME would enter the MEC information on to the CMV Driver Medical Examination Results Form, MCSA–5850, and submit it to the National Registry via the ME's password-protected web account by close of business the same day. For CMV drivers required to have CDLs or (after July 8, 2014) CLPs, FMCSA would then be able to promptly transmit to the SDLAs the drivers' MEC information for entry on the CDLIS driver records.

1. Summary of Estimated Costs

The Agency expects this proposed rule to generate net cost savings because of the reduced annual paperwork burden hours on the current IC. The additional cost this proposed rule would impose would result from the ME entering the CMV Driver Medical Examination Results Form, MCSA–5850, data more frequently into the National Registry System, as detailed in the revised Medical Qualifications Requirements Supporting Statement (Office of Management and Budget (OMB) Control Number 2126–0006) posted in the docket. This annual cost is very minimal in the amount of $455,994 (25,333 additional data entry annual burden hours × $18.00 per hour (includes benefits) for ME administrative personnel to perform data entry.) Another potential cost may be SDLAs' IT upgrades to connect to the National Registry database; however, the Agency is unable to estimate and quantify that potential cost at this time. The cost savings will be in the form of saving efficiencies through the electronic transmission of information.

2. Summary of Estimated Benefits

Potential quantifiable estimated benefits, as detailed in the revised Medical Qualification Requirements and the Commercial Driver Licensing and Test Standards (OMB control number 2126–0011) Supporting Statements-posted in the docket include: (1) Employers would no longer be required to verify the ME's National Registry number for CDL driver examinations because only MEs listed on the National Registry will be able to forward MEC information to the National Registry. MEs will encourage drivers to review and correct MEC information to ensure accurate information is recorded. This will result in $4.22 million in a cost savings to employers (221,904 annual burden hours × $19.00 per hour (including benefits)); (2) CMV drivers will save time by not having to provide their MEC to the SDLAs. By sending the MEC and variance information (as defined in the **SUMMARY** section) electronically FMCSA is creating a cost savings for drivers of $2.17 million (4,623,000 MECs × $0.47 postage to

SDLAs);[4] (3) SDLAs would save 205,333 annual burden hours of administrative time recording MEC information for not having to attend to the driver above, resulting in $3.69 million (205,333 annual burden hours × $18.00 per hour (including benefits)) in cost savings. As a result, this proposed rule will generate $10.1 million in overall cost savings.

Although the safety benefits of this rule are difficult to fully quantify, the Agency believes that the fraud prevention in electronic transmission of MEC and medical variance information (as defined in the **SUMMARY** section) will continue to improve safety on public roads. Continuing to leave the responsibility to drivers would create a potential for fraud, as it would provide an opportunity for the driver to forge or alter the MEC or medical variance information (as defined in the **SUMMARY** section). Prompt and complete reporting to FMCSA by the MEs would allow the information to be transmitted expeditiously to the SDLAs for posting on the CDLIS driver record for CDL and CLP drivers. As a result, up-to-date and accurate information concerning the medical certification status of such drivers would be available to State and Federal enforcement personnel, SDLAs, employers, drivers and others who rely on this information to determine whether a driver is in compliance with the applicable physical qualification standards.

Lastly, by using the new MER Form, MCSA–5875, FMCSA believes that MEs will be able to determine more correctly whether CMV drivers meet the physical qualification standards contained in 49 CFR 391.41(b). The MER Form, MCSA–5875, removes the advisory criteria (guidance) contained in the current form that has been sometimes confused with regulatory standards; contains evaluation tools that align more precisely with the qualification standards and the Agency's advisory criteria and presents those tools using a systematic physical examination approach similar to standards of clinical practice. When combined with the expected improvement in ME qualifications and performance under the National Registry program, the new form will help ensure that the physical condition of CMV operators is adequate to enable them to operate CMVs safely. Because the implementation of the National Registry program is just beginning, FMCSA does not have sufficient data at this time to quantify the expected safety benefits from adoption of the new MER Form, MCSA–5875.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and 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.[5] Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses.

Under the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), the proposed rule is not expected to have a significant economic impact on a substantial number of small entities. Consequently, I certify that the proposed action would not have a significant economic impact on a substantial number of small entities.

An Initial Regulatory Flexibility Analysis (IRFA), which must accompany this NPRM, must include six components. See 5 U.S.C. 603(b) and (c). The Agency has listed these components and addresses each section with regard to this NPRM.

1. A description of the reason why action by the Agency is being considered.

In order to alleviate manual entry of data by the SDLAs and to provide authorized State and Federal enforcement officials the most current and accurate information regarding the medical status of the CMV driver, FMCSA proposes to require MEs to begin using a newly developed MER Form, MCSA–5875, in place of the current MER Form. In addition, MEs would be required to report results of all driver physical examinations to FMCSA by close of business the day the examination is conducted by completing a CMV Driver Medical Examination Results Form, MCSA–5850, via their individual password-protected National Registry web account. FMCSA also proposes to transmit information from the MEC electronically from the National Registry to the SDLAs for CMV drivers who hold or apply for CLPs or CDLs and are required to be medically certified. It is also transmitting medical variance information (as defined in the **SUMMARY** section) for such drivers electronically to the SDLAs.

2. A succinct statement of the objectives of, and legal basis why action by the Agency is being considered.

The Agency's Medical Examiner's Certification Integration Rule is a follow-on rule that strengths and modifies the rules adopted in both the National Registry of Certified Medical Examiners published on April 20, 2012 (77 FR 2410) and the Medical Certification Requirements as Part of the CDL rule (Med-Cert rule) published on December 1, 2008 (73 FR 73096). It proposes to expedite transmission of the medical examination information to FMCSA by MEs, FMCSA would then promptly and accurately transmitted this information to the SDLAs electronically (for drivers required to have a CDL) to be entered into the appropriate CDLIS driver records. This rule is the third element of an initiative to improve the driver qualification and medical examiner certificate process. In addition, electronic transmission of the information will improve safety on public roads by decreasing the risk of fraud by CMV drivers and providing authorized State/Federal enforcement officials access to current and accurate medical status of CMV drivers during inspections.

3. A description and, where feasible, an estimate of the number of small entities to which the proposed rule would apply.

States have distinctive guidelines on who can perform physical examinations of commercial drivers, which vary among states for the purpose of certifying or non-certifying CDL drivers for this proposal, Federal regulations enable any of the following health-care professionals, including others, to conduct the CMV driver examination provided they are licensed, registered, or certified by the State(s) to conduct physical examinations: Medical Doctor (MD), Doctor of Osteopathy (DO), Physician Assistant (PA), Advanced Practice Nurses (APN) and Doctors of Chiropractic (DC). Once a year the Department of Labor's Bureau of Labor Statistics (BLS) publishes total annual employment figures based on their National Occupational Employment and Wage Estimates.[6] Therefore, the Agency

[4] OMB control number 2126–0011 Medical Qualification Requirements due to expire July 31, 2015. The number of medical certificates 4,623,000 issued per year by MEs × $0.47 ($0.05 copy + $0.42 postage) = $2,172,180.

[5] Regulatory Flexibility Act (5 U.S.C. 601 et seq.) see National Archives at *http://www.archives.gov/federal-register/laws/regulatory-flexibility/601.html*

[6] U.S. Department of Labor, Bureau of Labor Statistics (BLS). *May 2008 National Occupational Employment and Wage Estimates.* Available online

estimates that this rule would impact approximately 40,000 health-care professionals expected to be listed on the National Registry. (see National Registry of Certified Medical Examiners 77 FR 24104, April 20, 2012).

The Small Business Administration's threshold to qualify as a small business fluctuates between $10 million or less in revenue for physician-owned businesses to $7 million in revenue for APN and PA owned companies. As such, FMCSA considers all of the medical professionals as small entities.

4. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to requirements and the type of professional skills necessary for preparation of the report or record.

The ME will be required to fill out the MER Form, MCSA–5875, with examination findings and the CMV Driver Medical Examination Results Form, MCSA–5850, with the driver examination results. The skills required to fill out these forms are basic office and computer proficiency skills.

5. Identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

The Agency did not identify any Federal rules that duplicate, overlap or conflict with the rule.

6. A description of any significant alternatives to the proposed rule which minimize any significant impacts on small entities.

The Agency did not identify any significant alternatives to the rule that could lessen the burden on small entities without compromising its goals or the Agency's statutory mandate. Because small businesses are such a large part of the demographic the Agency regulates, providing alternatives to small businesses for non-compliance with FMCSA regulations or providing alternative compliance options is not feasible and not consistent with sound public policy.

C. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance; please consult the FMCSA point of contact, Elaine Papp, listed in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's 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 FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

D. Unfunded Mandates Reform Act of 1995

This proposed rule would have very minimal costs that would not exceed the threshold nor impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532 et seq.), that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $143.1 million (which is the value of $100 million in 2010 after adjusting for inflation) or more in any 1 year.

E. E.O. 13132 (Federalism)

A rule has implications for Federalism under Section 1(a) of Executive Order 13132 if it has ''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.'' FMCSA has determined that this proposal would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

F. E.O. 12988 (Civil Justice Reform)

This proposed rule meets applicable standards in sections 3(a) and 3(b) (2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminates ambiguity, and reduce burden.

G. E.O. 13045 (Protection of Children)

E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, Apr. 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this proposed rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

H. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this proposed rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it will not effect a taking of private property or otherwise have taking implications.

I. Privacy Impact Assessment

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. This rule does require the collection of personally identifiable information (PII). The supporting PIA, available for review in the docket, gives a full and complete explanation of FMCSA practices for protecting PII in general and specifically in relation to this proposed rule.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency which receives records contained in a system of records from a Federal agency for use in a matching program.

J. E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

K. Paperwork Reduction Act

This NPRM contains the following new IC requirements. As required by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)), FMCSA submitted the information requirements associated with the proposal to the OMB for its

at *http://www.bls.gov/oes/current/_oesnat.htm#b29-0000*. 2008.

review. This proposed rule has a decrease in annual paperwork burden hours (401,904 hours) as detailed in OMB control number 2126–0011 Commercial Driver Licensing and Test Standards and 2126–0006 Medical Qualification Requirements Supporting Statements in the docket.

Once the National Registry is implemented beginning May 21, 2014, as discussed in the final rule (77 FR 24104; April 21, 2012), MEs will start to electronically submit MEC information to the National Registry on a monthly basis. The Medical Examiner's Certification Integration Rule proposes that the information be submitted by the ME at the close of business the day the examination is conducted as opposed to submitting monthly batched reports. In addition, it proposes that FMCSA will electronically transmit examination information to the SDLAs, providing more accurate and timely delivery of information to update CDLIS driver records and for safety enforcement purposes. The requirements imposed on CMV drivers and employers for this IC are being considered. The estimate of the number of CMV drivers (respondents) covered by this IC includes both interstate drivers subject to the FMCSRs and intrastate drivers subject to compatible State regulations. Although Federal regulations do not require States to comply with the medical requirements in the FMCSRs, most States do mirror the Federal requirements. Close tracking and monitoring of certification activities and medical results are crucial to reducing fraudulent efforts of a subset of CDL applicants. Some CDL drivers avoid following the proper guidelines to become medically qualified, posing extreme risks to the public.

FMCSA analyzed this rule and determined that its implementation will decrease the currently approved IC burden hours covered by OMB Control No. 2126–006, titled ''Medical Qualification Requirements,'' and OMB Control No. 2126–0011, titled ''Commercial Driver Licensing and Test Standards.'' The Table below captures the current and future paperwork burden hours associated with the two approved supporting statements. A detailed analysis of each IC activity can be found in the Supporting Statements attachments, which are in the public docket for this rulemaking.

CURRENT AND FUTURE INFORMATION COLLECTION BURDENS

OMB Approvals No.	Currently approved annual burden hours	Future change in annual burden hours	Proposed annual burden hours for IC activities in year 4 and subsequent years
2126–0006	2,130,702	(196,571)	1,934,131
2126–0011	1,682,582	(205,333)	1,423,249
Totals	3,813,284	(401,904)	3,357,380

2126–0006 Medical Qualification Requirements.

This IC is currently due to expire on July 31, 2015. This revision is due to the Agency's development of the rules proposed in this NPRM. It proposes to change the State requirement of posting the original or copy of the MEC information to the CDLIS driver record within 10 calendar days of receipt to the posting of the electronic MEC information to the CDLIS driver record within 1 business day. In addition, the proposed rule would eliminate the requirement for the CMV drivers to provide their MEC to their SDLAs. It would also eliminate the requirement for motor carriers to verify that their CDL drivers were certified by an ME on the National Registry.

The current and proposed IC activities imposed on the MEs and motor carriers over the first 3 years of implementing the proposed electronic transmission of MEC information from the ME to the SDLAs would remain unchanged. This would allow time for those States that need to pass legislation and for all States to make the necessary system upgrades, before the proposed electronic transmission of MEC information from the ME, through the National Registry System, to the SDLA for update on the CDLIS driver's record will be implemented in each State and the District of Columbia. The table below details the IC activities incurred by the ME and motor carriers for the current and proposed first 3 years, along with IC activities in Year 4 and subsequent years.

Current and proposed IC activities for MEs and motor carriers	Currently approved annual burden hours	Proposed annual burden hours for the IC activities in first 3 years	Proposed annual burden hours for IC activities in year 4th and subsequent years
MER, Medical Examination Results Form, and the MEC	1,695,000	1,695,000	1,695,000
Resolution of Medical Conflict	11	11	11
SPE	192	192	192
Vision Exemption	727	727	727
Diabetes Exemption	600	600	600
ME Application	1,111	1,111	1,111
ME Test Results	1,111	1,111	1,111
CMV Driver Examination Data	123,575	123,575	148,908
MER and MEC Copies	175	175	175
Verification of National Registry Number	308,200	308,200	86,296
Total Burden Hours	2,130,702	2,130,702	1,934,131

FMCSA estimates that the number of times per year that respondents would provide CMV driver examination results information would increase from a minimum of 12 times per year to an average of 50 times per year. MEs would file 4,623,000 MECs per year (unchanged). It is projected that 40,000 MEs (unchanged) will be needed to perform the 4,623,000 CMV driver medical examinations required annually. The transmission of CMV driver examination information will require approximately 71,858 hours of ME administrative personnel time on a yearly basis [40,000 registered MEs × 1 minute/60 minutes to file a report × 50 reports per year + 4,623,000 reports × 30 seconds/3600 seconds to enter each driver's examination data elements = 71,858 hours]. This is an increase of 25,333 burden hours per year.

In addition, verification for CDL drivers will not be required, because FMCSA will provide medical certification information to the states only from MEs who are listed on the National Registry. Motor carriers will verify the National Registry Number for an estimated 1,294,440 non-CDL drivers who are medically certified per year (a decrease from 4,623,000 CDL and non-CDL drivers medically certified per year). It is estimated it will take motor carrier administrative personnel 4 minutes to verify the National Registry Number, write a note regarding the verification, and file the note in the DQ file, so this will require approximately 86,296 hours of administrative personnel time on a yearly basis [1,294,440 verifications × 4 minutes/60 minutes per verification = 86,296 hours]. This is a decrease of 221,904 annual burden hours per year.

FMCSA estimates that the Medical Examiner's Certification Integration Rule would decrease the total estimated annual time burden to respondents for Medical Qualifications by 196,571 hours [(221,904) fewer hours for verification of non-CDL National Registry Number minus 25,333 additional hours to enter driver examination data elements]. The Medical Examiner's Certification Integration Rule would result in a total annual time burden to respondents for all medical requirement components of an estimated 1, 934,131 hours (2,130,702 current hours minus 196,571 fewer hours).

2126–0011 Commercial Driver Licensing and Test Standards. This IC is currently due to expire on August 31, 2014. This IC supports the DOT Strategic Goal of Safety by requiring that CLP and CDL holders driving CMVs subject to part 391 are properly licensed according to all applicable Federal requirements. The information being collected ensures that CLP and CDL holders are qualified to hold a CLP or CDL to operate CMVs, and that States are administering their CDL programs in compliance with the Federal requirements.

As proposed, the MEC and medical variance information (as defined in the **SUMMARY** section) for CLP and CDL drivers would be transmitted electronically by FMCSA to the SDLA and posted to the CLP or CDL holder's CDLIS driver record. This would eliminate the need for the driver to carry a paper copy of the MEC and to physically provide a copy to his/her SDLA. Therefore, there would be no change in the total annual burden hours during the first 3 years. However, during these 3 years there will be a one-time cost that each State and the District of Columbia will need to expend to make updates to their systems to accommodate the development of the capability to electronically receive and post medical certification and medical variance information (as defined in the **SUMMARY** section) from FMCSA and to the CDLIS driver record. The information technology necessary to carry out these transactions are still in the early development stage. Therefore, FMCSA cannot make any cost estimates at this time. FMCSA welcomes any comments on estimated costs to develop this capability.

Starting in the 4th and subsequent years, there would be a proposed decrease in total annual burden hours due to the implementation of the new program change. With medical certification and medical variance information (as defined in the **SUMMARY** section) being sent electronically to the SDLA by FMCSA to post to the CDLIS driver record, the annual burden hours for the SDLA to manually post the medical certification and medical variance information to the CDLIS driver record will be reduced from 205,333 hours to 0 hours based on the medical variance information being electronically sent through the National Registry to the SDLA by FMCSA and electronically posted to the CDLIS driver record. If the medical variance information (as defined in the **SUMMARY** section) continues to be sent by email there would be minimal burden hours associated with this task therefore, FMCSA has not attempted to quantify it. The following table summarizes the annual information collection burden hours for current and proposed IC activities for the first 3 years and the subsequent years. As discussed above, the currently approved total annual burden of 1,628,582 hours for the first 3 years remains unchanged. The decrease in proposed total annual burden of 205,333 hours in subsequent years is due to the program changes from implementing the new requirement.

Current and proposed IC activities for States and CDL drivers	Currently approved annual burden hours	Proposed annual burden hours for the IC activities in first 3 years	Proposed annual burden hours for IC activities in year 4th and subsequent years
State recording of medical examiner's certification and medical variance information on CDLIS driver record	205,333	205,333	0
State recording of the self-certification of CMV operation on CDLIS driver record	3,984	3,984	3,984
State verification of the medical certification status of all interstate CDL holders	2,593	2,593	2,593
Driver to notify employer of convictions/disqualifications	640,000	640,000	640,000
Driver to complete previous employment paperwork	403,200	403,200	403,200
States to complete compliance certification documents	1,632	1,632	1,632
States to complete compliance review documents	2,400	2,400	2,400
Data/document checks and CDLIS recordkeeping	212,224	212,224	212,224
Drivers to complete the CLP/CDL application	48,000	48,000	48,000
CDL tests recordkeeping	84,000	84,000	84,000
Knowledge and skills test examiner certification	25,216	25,216	25,216
Skills test examiner monitoring and auditing	0	0	0

Current and proposed IC activities for States and CDL drivers	Currently approved annual burden hours	Proposed annual burden hours for the IC activities in first 3 years	Proposed annual burden hours for IC activities in year 4th and subsequent years
Total Burden Hours	1,628,582	1,628,582	1,423,249

L. National Environmental Policy Act and Clean Air Act

FMCSA analyzed this NPRM for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1(69 FR 9680, March 1, 2004), Appendix 2, paragraph (s)(7) and paragraph (t)(2). The Categorical Exclusion (CE) in paragraph (b) covers administrative or editorial changes; (s)(7) covers requirements for State-issued commercial license documentation; and paragraph (t)(2) addresses regulations that assure States have the appropriate information systems and procedures concerning CDL qualifications. The proposals in this rule are covered by these two CEs and the proposed action does not have any effect on the quality of the environment. The CE determination is available for inspection or copying in the Regulations.gov Web site listed under **ADDRESSES**. FMCSA also analyzed this rule under the Clean Air Act, as amended (CAA), section 176(c) (42 U.S.C. 7401 et seq.), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement since it does not affect direct or indirect emissions of criteria pollutants.

M. E.O. 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

N. E.O. 13175 (Indian Tribal Governments)

This rule does not have tribal implications under E.O. 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.

O. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

List of Subjects

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Incorporation by reference, Motor carriers.

49 CFR Part 384

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Incorporation by reference, Motor carriers.

49 CFR Part 391

Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons stated in the preamble, FMCSA proposes to amend title 49 CFR, Code of Federal Regulations, chapter III, to read as follows:

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 1. The authority citation for part 383 continues to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 et seq., and 31502; secs. 214 and 215, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 4140, Pub. L. 109–59, 119 Stat. 1144, 1746; and 49 CFR 1.87.

■ 2. Amend § 383.71 by revising paragraphs (h)(1) and (3) to read as follows:

§ 383.71 Driver application and certification procedures.

(h) * * *

(1) *New CLP and CDL applicants.* (i) Before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a new CLP or CDL applicant who certifies that he/she will operate CMVs in non-excepted, interstate commerce must provide the State with an original or copy (as required by the State) of a medical examiner's certificate prepared by a medical examiner, as defined in 49 CFR 390.5, and the State will post a medical qualifications status of ''certified'' on the CDLIS driver record for the driver;

(ii) On or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a new CLP or CDL applicant who certifies that he/she will operate CMVs in non-excepted, interstate commerce must be medically examined and certified in accordance with 49 CFR 391.43 as medically qualified to operate a CMV by a medical examiner, as defined in 49 CFR 390.5. Upon receiving an electronic copy of the medical examiner's certificate from FMCSA, the State will post a medical qualifications status of ''certified'' on the CDLIS driver record for the driver;

* * *

(3) *Maintaining the medical certification status of ''certified.''* (i) In order to maintain a medical certification status of ''certified,'' before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a CLP or CDL holder who

certifies that he/she will operate CMVs in non-excepted, interstate commerce must provide the State with an original or copy (as required by the State) of each subsequently issued medical examiner's certificate;

(ii) In order to maintain a medical certification status of ''certified,'' on or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a CLP or CDL holder who certifies that he/she will operate CMVs in non-excepted, interstate commerce must continue to be medically examined and certified in accordance with 49 CFR 391.43 as physically qualified to operate a commercial motor vehicle by a medical examiner, as defined in 49 CFR 390.5. FMCSA will provide the State with an electronic copy of the medical examiner's certificate information for all subsequent medical examinations in which the driver has been deemed qualified.

■ 3. Amend § 383.73 by revising paragraphs (a)(2)(vii), (b)(5), (o)(1), (o)(2), (o)(3) and (o)(4) to read as follows:

§ 383.73 State procedures.

(a) * * *

(2) * * *

(vii)(A) Before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for drivers who certified their type of driving according to § 383.71(b)(1)(ii)(A) (non-excepted interstate) and, if the CLP applicant submits a current medical examiner's certificate, date-stamp the medical examiner's certificate, and post all required information from the medical examiner's certificate to the CDLIS driver record in accordance with paragraph (o) of this section.

(B) On or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for drivers who certified their type of driving according to § 383.71(b)(1)(ii)(A) (non-excepted interstate) and, if FMCSA provides current medical examiner's certificate information electronically, post all required information matching the medical examiner's certificate to the CDLIS driver record in accordance with paragraph (o) of this section.

(b) * * *

(5)(i) Before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for drivers who certified their type of driving according to § 383.71(b)(1)(ii)(A) (non-excepted interstate) and, if the CDL holder submits a current medical examiner's certificate, date-stamp the medical examiner's certificate and post all required information from the medical examiner's certificate to the CDLIS driver record in accordance with paragraph (o) of this section.

(ii) On or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for drivers who certified their type of driving according to § 383.71(b)(1)(ii)(A) (non-excepted interstate) and, if FMCSA provides current medical examiner's certificate information electronically, post all required information matching the medical examiner's certificate to the CDLIS driver record in accordance with paragraph (o) of this section.

* * * * *

(o) *Medical recordkeeping* — (1)(i) *Status of CDL holder.* Before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for each operator of a commercial motor vehicle required to have a CLP or CDL, the current licensing State must:

(A) Post the driver's self-certification of type of driving under § 383.71(b)(1)(ii) to the CDLIS driver record;

(B) Post the information from the medical examiner's certificate within 10 calendar days to the CDLIS driver record, including:

(*1*) Medical examiner's name;

(*2*) Medical examiner's telephone number;

(*3*) Date of medical examiner's certificate issuance;

(*4*) Medical examiner's license number and the State that issued it;

(*5*) Medical examiner's National Registry identification number;

(*6*) The indicator of medical certification status, i.e., ''certified'' or ''not-certified'';

(*7*) Expiration date of the medical examiner's certificate;

(*8*) Existence of any medical variance on the medical examiner's certificate, such as an exemption, SPE certification, or grandfather provisions;

(*9*) Any restrictions (e.g., corrective lenses, hearing aid, required to have possession of an exemption letter or SPE certificate while on-duty, etc.); and

(*10*) Date the medical examiner's certificate information was posted to the CDLIS driver record; and

(C) Post the medical variance information within 10 calendar days to the CDLIS driver record, including:

(*1*) Date of medical variance issuance; and

(*2*) Expiration date of medical variance;

(D) Retain the original or a copy of the medical examiner's certificate of any driver required to provide documentation of physical qualification for 3 years beyond the date the certificate was issued.

(ii) *Status of CDL holder.* On or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for each operator of a commercial motor vehicle required to have a CLP or CDL, the current licensing State must:

(A) Post the driver's self-certification of type of driving under 49 CFR 383.71(b)(1)(ii) to the CDLIS driver record;

(B) Post the information from the medical examiner's certificate within 1 business day to the CDLIS driver record, including:

(*1*) Medical examiner's name;

(*2*) Medical examiner's telephone number;

(*3*) Date of medical examiner's certificate issuance;

(*4*) Medical examiner's license number and the State that issued it;

(*5*) Medical examiner's National Registry identification number;

(*6*) The indicator of medical certification status, i.e., ''certified'' or ''not-certified'';

(*7*) Expiration date of the medical examiner's certificate;

(*8*) Existence of any medical variance on the medical examiner's certificate, such as an exemption, Skill Performance Evaluation (SPE) certification, or grandfather provisions;

(*9*) Any restrictions (e.g., corrective lenses, hearing aid, required to have possession of an exemption letter or SPE certificate while on-duty, etc.); and

(*10*) Date the medical examiner's certificate information was posted to the CDLIS driver record;

(C) Post the medical variance information within 1 business day to the CDLIS driver record, including:

(*1*) Date of medical variance issuance; and

(*2*) Expiration date of medical variance;

(D)(*1*) Retain the electronic record of the medical examiner's certificate information for any driver required to have documentation of physical qualification for 3 years beyond the date the certificate was issued.

(*2*)(*i*) *Status update.* Until the day before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the State must, within 10 calendar days of the driver's medical examiner's certificate or medical variance expiring, the medical variance being rescinded or the medical examiner's certificate being voided by FMCSA, update the medical certification status of that driver as ''not certified.''

(*ii*) Beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE

OF THE FINAL RULE], the State must, within 10 calendar days of the driver's medical examiner's certificate or medical variance expiring, the medical examiner's certificate becoming invalid, the medical variance being rescinded or the medical examiner's certificate being voided by FMCSA, update the medical certification status of that driver as ''not certified.''

(3) *Variance update.* (i) Before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], within 10 calendar days of receiving information from FMCSA regarding issuance or renewal of a medical variance for a driver, the State must update the CDLIS driver record to include the medical variance information provided by FMCSA.

(ii) On or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], within 1 business day of electronically receiving medical variance information from FMCSA regarding the issuance or renewal of a medical variance for a driver, the State must update the CDLIS driver record to include the medical variance information provided by FMCSA.

(4) *Downgrade.* (i) if a driver's medical certification or medical variance expires, or FMCSA notifies the State that a medical certification or medical variance was removed or rescinded, the State must:

(A)(*1*) Before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE] notify the CLP or CDL holder of his/her CLP or CDL ''not-certified'' medical certification status and that the CMV privileges will be removed from the CLP or CDL unless the driver submits a current medical examiner's certificate and/or medical variance, or changes his/her self-certification to driving only in excepted or intrastate commerce (if permitted by the State);

(*2*) On or after [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE] notify the CLP or CDL holder of his/her CLP or CDL ''not-certified'' medical certification status and that the CMV privileges will be removed from the CLP or CDL unless the driver has been medically examined and certified in accordance with 49 CFR 391.43 as physically qualified to operate a commercial motor vehicle by a medical examiner, as defined in 49 CFR 390.5 of this chapter, or the driver changes his/her self-certification to driving only in excepted or intrastate commerce (if permitted by the State).

(B) [Reserved]

(ii) [Reserved]

* * * * *

PART 384—STATE COMPLIANCE WITH COMMERCIAL DRIVER'S LICENSE PROGRAM

■ 5. The authority citation for part 384 continues to read as follows:

Authority: 49 U.S.C. 31136, 31301, et seq., and 31502; secs. 103 and 215, Pub. L. 106–159, 113 Stat. 1748, 1753, 1767; and 49 CFR 1.87.

■ 6. Revise § 384.234 to read as follows:

§ 384.234 Driver medical certification recordkeeping.

The State must meet the medical certification recordkeeping requirements of §§ 383.73(a)(2)(vii), (b)(5), (c)(8), (d)(8), (e)(6) and (o) of this chapter.

■ 7. Amend § 384.301 by adding a new paragraph (i) to read as follows:

§ 384.301 Substantial compliance—general requirements.

* * * * *

(i) A State must come into substantial compliance with the requirements of subpart B of this part and part 383 of this chapter in effect as of [INSERT THE EFFECTIVE DATE OF THE FINAL RULE] as soon as practical, but, unless otherwise specifically provided in this part, not later than [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

PART 391—QUALIFICATIONS OF DRIVERS AND LONGER COMBINATION (LCV) DRIVER INSTRUCTORS

■ 8. The authority citation for part 391 will continue to read as follows:

Authority: 49 U.S.C. 504, 508, 31133, 31136, and 31502; sec. 4007(b), Pub. L. 102–240, 105 Stat, 1914, 2152; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215, Pub. L. 106–159, 113 Stat. 1748, 1767; and 49 CFR 1.87.

■ 9. Amend § 391.23 by revising paragraph (m)(2) to read as follows:

§ 391.23 Investigation and inquiries.

* * * * *

(m) * * *

(2) *Exception.* For drivers required to have a commercial driver's license under part 383 of this chapter:

(i) Beginning January 30, 2014, using the CDLIS motor vehicle record obtained from the current licensing State, the motor carrier must verify and document in the driver qualification file the following information before allowing the driver to operate a CMV:

(A) The type of operation the driver self-certified that he or she will perform in accordance with § 383.71(b)(1)(ii) of this chapter.

(B) (*1*) Beginning on May 21, 2014, and ending on [INSERT THE EFFECTIVE DATE OF THE FINAL RULE*],* that the driver was certified by a medical examiner listed on the National Registry of Certified Medical Examiners as of the date of medical examiner's certificate issuance.

(*2*) Beginning on [INSERT THE EFFECTIVE DATE OF THE FINAL RULE], if the driver has certified under paragraph (m)(2)(i)(A) of this section that he or she expects to operate in interstate commerce, that the driver has a valid medical examiner's certificate and any required medical variances.

(*3*) Beginning on July 8, 2014, if the driver has a commercial learner's permit and has certified under paragraph (m)(2)(i)(A) of this section that he or she expects to operate in interstate commerce that the driver has a valid medical examiner's certificate and any required medical variances.

(C) *Exception.* Until [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], if the driver provided the motor carrier with a copy of the current medical examiner's certificate that was submitted to the State in accordance with § 383.73(a)(5) of this chapter, the motor carrier may use a copy of that medical examiner's certificate as proof of the driver's medical certification for up to 15 days after the date it was issued.

(ii) [Reserved]

■ 10. Amend § 391.41 by revising paragraph (a)(2)(i) to read as follows:

§ 391.41 Physical qualifications for drivers.

(a) * * *

(2) *CDL exception.* (i) (A) Beginning January 30, 2014 and ending on the day before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a driver required to have a commercial driver's license under part 383 of this chapter, and who submitted a current medical examiner's certificate to the State in accordance with 49 CFR 383.71(h) documenting that he or she meets the physical qualification requirements of this part, no longer needs to carry on his or her person the medical examiner's certificate specified at § 391.43(h), or a copy, for more than 15 days after the date it was issued as valid proof of medical certification.

(B) Beginning on [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a driver required to have a commercial driver's license or a commercial learner's permit under 49 CFR part 383, and who has a current medical examiner's certificate documenting that he or she meets the physical qualification requirements of this part, is no longer permitted to carry on his or her person the medical

examiner's certificate specified at § 391.43(h).

* * * * *

■ 11. Amend § 391.43 by revising paragraphs (f), (g)(2), (g)(3) and (h), and adding paragraph (g)(4) and (g)(5), to read as follows:

§ 391.43 Medical examination; certificate of physical examination.

* * * * *

(f) The medical examination shall be performed, and its results shall be recorded on the Medical Examination Report set out below

Form MCSA-5875 (Revised: 04/01/2013) OMB No. 2126-0006 Expiration Date:

Public Burden Statement
A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2126-0006. Public reporting for this collection of information is estimated to be approximately 20 minutes per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Motor Carrier Safety Administration, MC-RRA, 1200 New Jersey Avenue, SE, Washington, D.C. 20590.

U.S. Department of Transportation
Federal Motor Carrier
Safety Administration

Medical Examination Report Form

(for Commercial Driver Medical Certification)

PRIVACY ACT STATEMENT *This statement is provided pursuant to the Privacy Act of 1974, 5 USC § 552a.*
AUTHORITY: Title 49, United States Code (USC), 49 USC 31136(a)(8) and 31149(c)(1)(E).
PURPOSE: To record results of a driver's physical examination to determine qualification to operate a commercial motor vehicle (CMV) in interstate commerce according to the requirements in 49 CFR 391.41-49. Providing this information is mandatory. If this information is not provided, the medical examiner will not be able to determine qualification to operate a CMV in interstate commerce according to the requirements in 49 CFR 391.41-49.
Medical examiners are required to complete the Medical Examination Report Form for every driver physical examination performed in accordance with 49 CFR 391.41. Each original (paper or electronic) completed Medical Examination Report Form must be retained on file at the office of the medical examiner for at least 3 years from the date of examination. The medical examiner must make all records and information in these files available to an authorized representative of FMCSA or an authorized Federal, State, or local enforcement agency representative, within 48 hours after the request is made (49 CFR 391.43(f)).
ROUTINE USES: The information is used for the purpose set forth above and may be forwarded to Federal, State, or local law enforcement agencies for their use. Medical Examination Report Forms collected by FMCSA will be stored in FMCSA's automated National Registry of Certified Medical Examiners System and will be used to monitor the performance of medical examiners listed on the National Registry.
In addition to those disclosures permitted under 5 USC 552a(b) of the Privacy Act of 1974, additional disclosures may be made in accordance with the U.S. Department of Transportation (DOT) Prefatory Statement of General Routine Uses published in the Federal Register on December 29, 2010 (75 FR 82171), under "Prefatory Statement of General Routine Uses" (available at http://www.dot.gov/privacy/privacyactnotices).
ACKNOWLEDGMENT: *I understand the provisions of the Privacy Act of 1974 as related to me through the above-mentioned statement.*

CMV Driver Signature: _____ Date: _____

MEDICAL RECORD #
_____
(or sticker)

SECTION 1. Driver Information *(to be filled out by the driver)*

PERSONAL INFORMATION

Last Name: _____ First Name: _____ Middle Initial: ____ Date of Birth: _____ Age: ___ Gender: ○ M ○ F

Address: _____ City: _____ State: ____ Zip Code: _____ Phone: _____

Driver License Number: _____ State of Issue: ____ Intrastate Only? ○ Yes ○ No CDL*? ○ Yes ○ No Driver ID Verified By**: _____

Has your USDOT/FMCSA medical certificate ever been denied or issued for less than 2 years? ○ Yes ○ No

DRIVER HEALTH HISTORY

Do you have or have your ever had:	Yes	No		Yes	No
1. Head/brain injuries or illnesses *(e.g., concussion)*	○	○	16. Dizziness, headaches, numbness, tingling, or memory loss	○	○
2. Seizures, epilepsy	○	○	17. Unexplained weight loss	○	○
3. Eye problems *(except glasses or contacts)*	○	○	18. Stroke, mini-stroke (TIA), paralysis, or weakness	○	○
4. Ear and/or hearing problems	○	○	19. Missing or limited use of arm, hand, finger, leg, foot, toe	○	○
5. Heart disease, heart attack, bypass, or other heart problems	○	○	20. Neck or back problems	○	○
6. Pacemaker, stents, implantable devices, or other heart procedures	○	○	21. Bone, muscle, joint, or nerve problems	○	○
7. High blood pressure	○	○	22. Blood clots or bleeding problems	○	○
8. High cholesterol	○	○	23. Cancer	○	○
9. Chronic cough, shortness of breath, or other breathing problems	○	○	24. Chronic infection or other chronic diseases	○	○
10. Lung disease *(e.g., asthma)*	○	○	25. Problems staying awake, loud snoring	○	○
11. Kidney problems, kidney stones, or pain/problems with urination	○	○	26. Sleep apnea	○	○
12. Stomach, liver, or digestive problems	○	○	27. Have you ever had a sleep test *(e.g., sleep apnea)*?	○	○
13. Diabetes or blood sugar problems	○	○	28. Have you ever spent a night in the hospital?	○	○
14. Anxiety, depression, nervousness, other mental health problems	○	○	29. Have you ever been treated for mental health problems?	○	○
15. Fainting or passing out	○	○	30. Have you ever had a broken bone?	○	○
31. Have you ever had surgery? If "yes," please list and explain below.	○	○	32. Other health condition(s) not described above	○	○
33. Are you currently taking medications *(prescription, over-the-counter, herbal, diet supplements)*? If "yes," please describe below.	○	○	34. Did you answer "yes" to any of questions 1-30? If so, please comment further on those health conditions below.	○	○

(Attach additional sheets if necessary)

*CDL Yes/No: Commercial driver's license (CDL) means a license issued to an individual by a State or other jurisdiction of domicile, in accordance with the standards contained in 49 CFR part 383, which authorizes the individual to operate a class of a commercial motor vehicle. CDL includes a commercial learner's permit (CLP). Check yes if the person is a CDL holder or is applying to become a CDL holder.

**Driver ID Verified By: Record what type of photo ID was used to verify the identity of the driver, e.g., CDL, driver's license, passport.

Form MCSA-5875 (Revised: 04/01/2013)

Last Name: _____ First Name: _____ Middle Initial: ____ Date: _____ Page 2

DRIVER LIFESTYLE QUESTIONS

	Yes	No		Yes	No
35. Have you ever used or do you now use tobacco?	○	○	37. Have you used an illegal substance within the past 2 years?	○	○
36. Do you currently drink alcohol?	○	○	38. Have you ever failed a drug test or been dependent on an illegal substance?	○	○

DRIVER SIGNATURE

A driver is expected to provide the medical examiner with an accurate and complete medical history, as indicated in this Form that is part of 49 CFR 391.43. A driver who provides fraudulent or intentionally false information is in violation of 49 CFR 390.35, and would be subject to the penalties under 49 CFR 390.37.

Driver's Signature: _____ Date: _____

SECTION 2. Examination Report *(to be filled out by the medical examiner)*

Review and discuss pertinent driver answers and any available medical records

Comment on the driver's responses to the "health history" questions that may affect the driver's safe operation of a commercial motor vehicle (CMV).

(Attach additional sheets if necessary)

TESTING

Last Name: _____ First Name: _____ Middle Initial: ____ Height: ___ *feet* ___ *inches* Weight: ____ *pounds*

Neck circumference *(optional)**: ___ *inches* BMI *(optional)**: ___ Pulse rate: _____ Pulse rhythm regular: ○ Yes ○ No

**(Please note that a neck circumference greater than 17" for men/16" for women OR a body mass index greater than 33 are both risk factors for sleep apnea.)*

Blood Pressure	Systolic	Diastolic
Sitting		
Second reading (optional)		

Urinalysis	Sp. Gr.	Protein	Blood	Sugar
Urinalysis is required. Numerical readings must be recorded.				

Protein, blood, or sugar in the urine may be an indication for further testing to rule out any underlying medical problem.

Other testing if indicated *(e.g., A1C, EKG; see FMCSA guidance)*

Vision

Standard is at least 20/40 acuity (Snellen) in each eye with or without correction. At least 70° field of vision in horizontal meridian measured in each eye. The use of corrective lenses should be noted on the Medical Examiner's Certificate.

Acuity	Uncorrected	Corrected	Horizontal Field of Vision
Right Eye:	20/____	20/____	Right Eye: ____ degrees
Left Eye:	20/____	20/____	Left Eye: ____ degrees
Both Eyes:	20/____	20/____	

	Yes	No
Applicant can recognize and distinguish among traffic control signals and devices showing red, green, and amber colors	○	○
Monocular vision	○	○
Referred to ophthalmologist or optometrist?	○	○
Received documentation from ophthalmologist or optometrist?	○	○

Hearing

Standard: Must first perceive whispered voice at greater than 5 feet (with or without hearing aid **OR** *average hearing loss in better ear at less than 40 dB.*

Check if hearing aid used for test: ○ Right Ear ○ Left Ear ○ Neither

Whisper Test Results	Right Ear	Left Ear
Record distance *(in feet)* from driver at which a forced whispered voice can first be heard	_____	_____

OR

Audiometric Test Results

Right Ear			Left Ear		
500 Hz	1000 Hz	2000 Hz	500 Hz	1000 Hz	2000 Hz
_____	_____	_____	_____	_____	_____

Average (right): _____ Average (left): _____

Form MCSA-5875 (Revised: 04/01/2013)

Last Name: _____ First Name: _____ Middle Initial: ____ Date: _____ Page 3

PHYSICAL EXAMINATION

The presence of a certain condition may not necessarily disqualify a driver, particularly if the condition is controlled adequately, is not likely to worsen, or is readily amenable to treatment. Even if a condition does not disqualify a driver, the Medical Examiner may consider deferring the driver temporarily. Also, the driver should be advised to take the necessary steps to correct the condition as soon as possible, particularly if neglecting the condition could result in a more serious illness that might affect driving.

Check if the body system is normal, or if there are any abnormalities. Discuss any abnormal answers in detail in the space below and indicate whether it would affect the driver's ability to operate a CMV. Enter applicable item number before each comment. If organic disease is present, note if it has been compensated for.

Body System	Normal	Abnormal	Body System	Normal	Abnormal
1. General	○	○	8. Abdomen	○	○
2. Skin	○	○	9. Inguinal hernia *(male only)*	○	○
3. Eyes	○	○	10. Back	○	○
4. Ears	○	○	11. Extremities/joints	○	○
5. Mouth/throat	○	○	12. Spine	○	○
6. Heart	○	○	13. Neuro/reflexes	○	○
7. Lungs/chest	○	○	14. Gait	○	○

Impressions:

(Attach additional sheets if necessary)

MEDICAL EXAMINER DETERMINATION

○ Meets standards in 49 CFR 391.41; qualifies for 2-year certificate

○ Does not meet standards *(explain why)*: _____

○ Meets standards, but periodic monitoring required *(due to)*: _____

Driver qualified for: ○ 3 months ○ 6 months ○ 1 year ○ other: _____

☐ Wearing corrective lenses ☐ Wearing hearing aid

☐ Accompanied by a waiver/exemption *(Driver must present exemption certificate at time of certification)*

☐ Accompanied by a Skill Performance Evaluation (SPE) certificate

☐ Driving within an exempt intracity zone *(see 49 CFR 391.62)*

☐ Qualified by operation of 49 CFR 391.64

If the driver meets the standards outlined in 49 CFR 391.41, then complete a Medical Examiner's Certificate as stated in 49 CFR 391.43(h), as appropriate.

I have performed this evaluation for certification. I have personally reviewed all available records and recorded information pertaining to this evaluation, and attest that to the best of my knowledge, I believe it to be true and correct.

Medical Examiner Signature: _____ Medical Examiner Name: _____ Date: _____

Address: _____ City: _____ State: ____ Zip Code: _____ Phone: _____

Medical Examiner's License or Certificate Number: _____ ☐ MD ☐ DO ☐ Physician Assistant ☐ Chiropractor

State issuing License or Certificate: _____ ☐ Advanced Practice Nurse ☐ Other Practitioner

National Registry Number: _____ Medical Certificate Expiration Date: _____

Determination pending *(specify reason)*: _____

Return to medical exam office for follow-up on *(must be 45 days or less)*: _____

Comment on reasons for amendment: _____

(if amended) Medical Examiner Signature: _____ Date: _____

BILLING CODE C

(g) * * *

(2) (i) Until the day before [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], if the medical examiner finds that the person examined is physically qualified to operate a commercial motor vehicle in accordance with § 391.41(b), he or she must complete a certificate in the form prescribed in paragraph (h) of this section and furnish the original to the person who was examined. The examiner must provide a copy to a prospective or current employing motor carrier who requests it.

(ii) Beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], if the medical examiner identifies that the person examined will not be operating a commercial motor vehicle that requires a commercial driver's license or a commercial learner's permit and finds that the driver is physically qualified to operate a commercial motor vehicle in accordance with § 391.41(b), he or she must complete a certificate in the form prescribed in paragraph (h) of this section and furnish the original to the person who was examined. The examiner must provide a copy to a prospective or current employing motor carrier who requests it.

(3) Beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], if the medical examiner finds that the person examined is not physically qualified to operate a commercial motor vehicle in accordance with § 391.41(b), he or she must inform the person examined that

he or she is not physically qualified, and that this information will be reported to FMCSA. All medical examiner's certificates previously issued to the person are not valid and no longer satisfy the requirements of § 391.41(a).

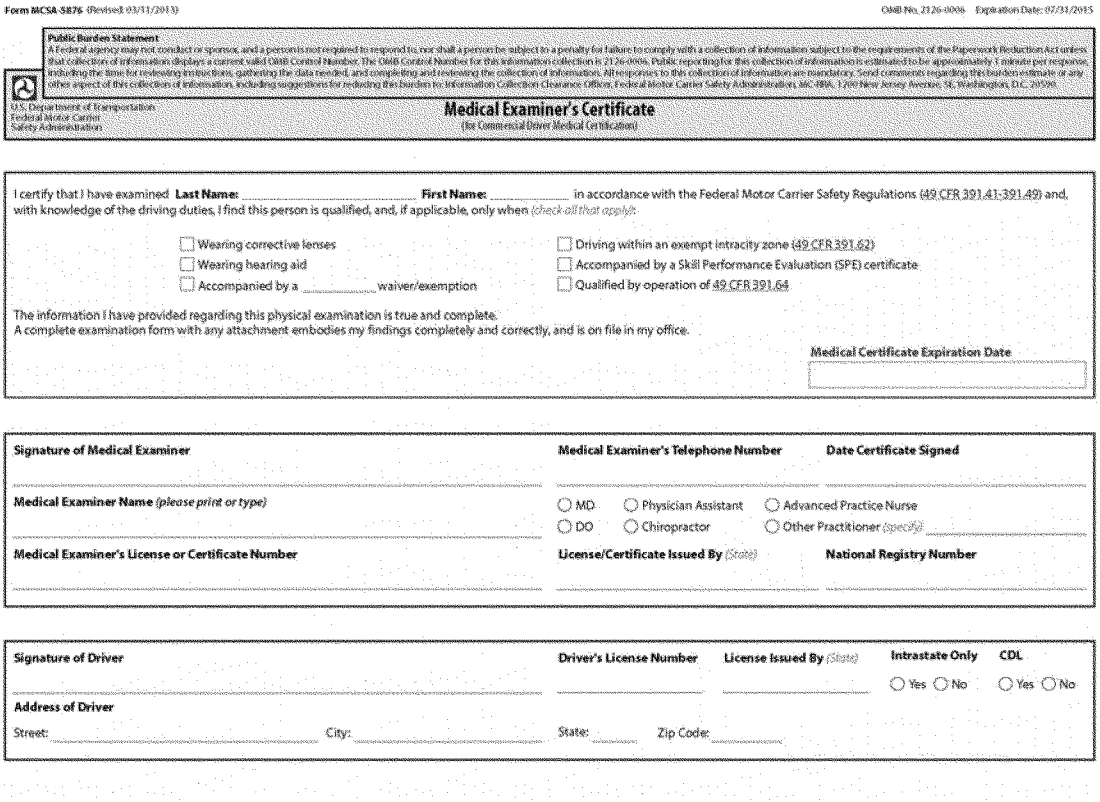
(4) Beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], if the medical examiner finds that the determination of whether the person examined is physically qualified to operate a commercial motor vehicle in accordance with § 391.41(b) should be delayed pending the receipt of additional information or the conduct of further examination in order for the medical examiner make such determination, he or she must inform the person examined that the additional information must be provided or the further examination completed within 45 days, and that the pending status of the examination will be reported to FMCSA.

(5)(i)(A) Once every calendar month, beginning May 21, 2014 and ending on [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], the medical examiner must electronically transmit to the Director, Office of Carrier, Driver and Vehicle Safety Standards, via a secure Web account on the National Registry, a completed CMV Driver Medical Examination Results Form, MCSA–5850, Medical Examiner Submission of CMV Driver Medical Examination Results. The Form must include all information specified for each medical examination conducted during the previous month for any driver who is required to be examined by a medical examiner listed on the National Registry of Certified Medical Examiners.

(B) Beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE] by close of business on each day during which the medical examiner completes a medical examination for any driver who is required to be examined by a medical examiner listed on the National Registry of Certified Medical Examiners the medical examiner must electronically transmit the Director, Office of Carrier, Driver and Vehicle Safety Standards, via a secure FMCSA-designated Web site, a completed CMV Driver Medical Examination Results Form, MCSA–5850, Medical Examiner Submission of CMV Driver Medical Examination. The Form must include all information specified for each medical examination conducted for each driver.

(ii) Beginning on May 21, 2014, if the medical examiner does not perform a medical examination of any driver who is required to be examined by a medical examiner listed on the National Registry of Certified Medical Examiners during any calendar month, the medical examiner must report that fact to FMCSA, via a secure FMCSA-designated Web site, by the close of business on the last day of such month.

(h) The medical examiner's certificate shall be completed in accordance with the following Form MCSA–5876, Medical Examiner's Certificate.



Form MCSA-5876 (Revised 03/31/2013) OMB No. 2126-0006 Expiration Date: 07/31/2015

Public Burden Statement
A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2126-0006. Public reporting for this collection of information is estimated to be approximately 1 minute per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Motor Carrier Safety Administration, MC-RRA, 1200 New Jersey Avenue, SE, Washington, D.C. 20590.

U.S. Department of Transportation
Federal Motor Carrier
Safety Administration

Medical Examiner's Certificate
(for Commercial Driver Medical Certification)

I certify that I have examined **Last Name:** _____ **First Name:** _____ in accordance with the Federal Motor Carrier Safety Regulations (49 CFR 391.41-391.49) and, with knowledge of the driving duties, I find this person is qualified, and, if applicable, only when *(check all that apply)*:

- ☐ Wearing corrective lenses
- ☐ Wearing hearing aid
- ☐ Accompanied by a _____ waiver/exemption
- ☐ Driving within an exempt intracity zone (49 CFR 391.62)
- ☐ Accompanied by a Skill Performance Evaluation (SPE) certificate
- ☐ Qualified by operation of 49 CFR 391.64

The information I have provided regarding this physical examination is true and complete.
A complete examination form with any attachment embodies my findings completely and correctly, and is on file in my office.

Medical Certificate Expiration Date

Signature of Medical Examiner | **Medical Examiner's Telephone Number** | **Date Certificate Signed**

Medical Examiner Name *(please print or type)*

○ MD ○ Physician Assistant ○ Advanced Practice Nurse
○ DO ○ Chiropractor ○ Other Practitioner *(specify)* _____

Medical Examiner's License or Certificate Number | **License/Certificate Issued By** *(State)* | **National Registry Number**

Signature of Driver | **Driver's License Number** | **License Issued By** *(State)* | **Intrastate Only** ○ Yes ○ No | **CDL** ○ Yes ○ No

Address of Driver
Street: _____ City: _____ State: _____ Zip Code: _____

* * * * *

■ 12. Amend § 391.45 by revising paragraphs (b)(2) and (c), and adding new paragraph (d) to read as follows:

§ 391.45 Persons who must be medically examined and certified.

* * * * *

(b) * * *

(2) Any driver authorized to operate a commercial motor vehicle only with an exempt intracity zone pursuant to § 391.62, or only by operation of the exemption in § 391.64, if such driver has not been medically examined and certified as qualified to drive in such zone during the preceding 12 months;

(c) Any driver whose ability to perform his/her normal duties has been

impaired by a physical or mental injury or disease; and

(d) Beginning [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], any person found by a medical examiner not to be physically qualified to operate a commercial motor vehicle under the provisions of paragraph (g)(3) of § 391.43.

■ 13. Amend § 391.51 by revising paragraphs (b)(7)(i) and (ii), and (b)(9) to read as follows:

§ 391.51 General requirements for driver qualification files.

* * * * *

(b) * * *

(7)(i) The medical examiner's certificate as required by § 391.43(g) or a legible copy of the certificate.

(ii) *Exception.* For CDL holders, beginning January 30, 2012, if the CDLIS motor vehicle record contains medical certification status information, the motor carrier employer must meet this requirement by obtaining the CDLIS motor vehicle record defined at § 384.105 of this chapter. That record must be obtained from the current licensing State and placed in the driver qualification file. After January 30, 2014 a non-excepted, interstate CDL holder without medical certification status information on the CDLIS motor vehicle record is designated ''not-certified'' to operate a CMV in interstate commerce. After January 30, 2014 and until [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], a motor carrier may use a copy of the driver's current medical examiner's certificate that was submitted to the State for up to 15 days from the date it was issued as proof of medical certification.

* * * * *

(9) (i) For drivers not required to have a CDL, a note relating to verification of medical examiner listing on the National Registry of Certified Medical Examiners required by § 391.23(m)(1).

(ii) Until [INSERT DATE 3 YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], for drivers required to have a CDL, a note relating to verification of medical examiner listing on the National Registry of Certified Medical Examiners required by § 391.23(m)(2).

* * * * *

Issued under the authority delegated in 49 CFR 1.87 on: May 2, 2013.

Anne S. Ferro,

Administrator.

[FR Doc. 2013–11080 Filed 5–9–13; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 78, No. 91
Friday, May 10, 2013

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 COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of 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

[5/2/2013 through 5/6/2013]

Firm name	Firm address	Date accepted for investigation	Product(s)
TNT Motorsports of Catawba Valley, Inc.	1095 6th Street Court SE, Hickory, NC 28602.	4/17/2013	The firm produces composite components; primary manufacturing materials include carbon fiber and fiber glass.
Lines Unlimited, Inc	715 Park Centre Drive, Kernersville, NC 27284.	4/18/2013	The firm produces laser cut wood panels, metal parts, and inlaid lines and curved borders primarily for the furniture industry.
J.C. Schultz Enterprises, Inc. (dba Flagsource).	951 Swanson Drive, Batavia, IL 60510.	4/15/2013	The firm manufacturers custom flags, banners and related accessories such as U.S. state flags, custom corporate banners, and international flags.

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: May 6, 2013.

Michael DeVillo,

Eligibility Examiner.

[FR Doc. 2013–11159 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1898]

Reorganization of Foreign-Trade Zone 241 Under Alternative Site Framework Fort Lauderdale, Florida

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the City of Fort Lauderdale, grantee of Foreign-Trade Zone 241, submitted an application to the Board (FTZ Docket B–48–2012, docketed 6/27/2012) for authority to reorganize under the ASF with a service area comprised of portions of Broward County, Florida (as described in the application), adjacent to the Port Everglades Customs and Border Protection port of entry, to modify Site 1 by removing acreage, to expand Sites 2 and 4, to remove Site 3 in its entirety from the zone, and to categorize FTZ 241's Sites 1, 2 and 4 as magnet sites and Site 5 as a usage-driven site;

Whereas, notice inviting public comment was given in the **Federal Register** (77 FR 39466–39467, 7/3/2012) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied with respect to the ASF reorganization, modification of Site 1 and removal of Site 3 (but not with respect to the proposed expansion of Sites 2 and 4);

Now, therefore, the Board hereby orders:

The application to reorganize and expand FTZ 241 under the ASF is approved in part (as it relates to the ASF reorganization, modification of Site 1 and removal of Site 3), subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, to a five-year ASF sunset provision for magnet sites that would terminate authority for existing Sites 2 and 4 if not activated by April 30, 2018, and to a three-year ASF sunset provision for usage-driven sites that would terminate authority for Site 5 if no foreign-status merchandise is admitted for a *bona fide* customs purpose by April 30, 2016.

Signed at Washington, DC, this 30th day of May 2013.

Paul Piquado,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2013–11203 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC680

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Council to convene a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will convene a meeting of the Standing, Special Mackerel and Ecosystem Scientific and Statistical Committees (SSC).

DATES: The meeting will convene at 8:30 a.m. on Wednesday, May 29, 2013 and conclude by 12 p.m. Friday, May 31, 2013.

ADDRESSES: The meeting will be held at the Renaissance International Plaza Hotel, 4200 Jim Walter Boulevard, Tampa, FL 33607; telephone: (813) 877–9200.

Council address: Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Steven Atran, Population Dynamics Statistician; Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The Standing, Special Mackerel and Special Reef Fish SSCs will initially meet jointly on Wednesday, May 29, 2013 to elect a chair and vice chair. Afterwards, the Standing and Special Mackerel SSC will review the final results of the SEDAR 28 cobia and Spanish mackerel benchmark assessments. The SSC previously reviewed the assessments at its March 27–28, 2013 meeting, but was unable to recommend acceptable biological catch (ABC) levels because a number of questions remained on the use of certain parameters necessary to produce the probability distribution functions (PDFs) needed to determine overfishing limit (OFL) and ABC. These included whether to use a proxy value for the fishing mortality rate at maximum sustainable yield (MSY), what value to use for the steepness of the spawner-recruit curve, and how to incorporate uncertainty with respect to the natural mortality rate estimate into the results. The analysts sought advice from the SSC at the March meeting, where it was determined that a proxy based on 30% spawning potential ratio should be used for the fishing mortality rate at MSY, a fixed steepness value of 0.8 be used for the spawner-recruit curve, and a weighted average of PDFs under several estimates of natural mortality be used to account for the uncertainty. Based on the completed analyses, the SSC will determine whether to accept the assessments, and if accepted, will recommend ABC for cobia and Spanish mackerel. The SSC will also review terms of reference for the upcoming SEDAR 38 (king mackerel) benchmark assessment, and will solicit for participants in SEDAR 38 workshops.

Following the Standing and Special Mackerel SSC session, the Standing and Special Reef Fish SSC will meet for the remainder of the meeting on Wednesday, May 29, 2013 through Friday, May 31, 2013. The SSC will receive a presentation on SEDAR 31 red snapper benchmark assessment; determine whether to accept the assessment, and if accepted, will recommend ABC for red snapper that is consistent with the rebuilding plan. The SSC will also discuss the impact of explosive oil and gas rig removals on the red snapper stock. Copies of the agenda and other related materials can be obtained by calling (813) 348–1630 or can be downloaded from the Council's ftp site, *ftp.gulfcouncil.org.*

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committees will be restricted to those issues specifically identified in the agenda 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 Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council (see **ADDRESSES**) at least 5 working days prior to the meeting.

Dated: May 7, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–11151 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC678

North Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The North Pacific Fishery Management Council's (Council) Observer Advisory Committee (OAC) will meet in Juneau, AK.

DATES: The meetings will be held on June 3, 2013, from 8 a.m. to 5 p.m., and June 4, 2013, from 8 a.m. to 12 p.m.

ADDRESSES: The meetings will be held at NMFS, Federal Building, 709 W 9th Street, 4th Floor, Regional Conference Room, Juneau, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Chris Oliver, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The agenda items include: Receive the report on the 2013 performance evaluation; review the electronic monitoring strategic plan; review regulatory amendment proposals already submitted for consideration, and develop recommended criteria for Council consideration.

The Agenda is subject to change, and the latest version will be posted at *http://www.alaskafisheries.noaa.gov/npfmc/*.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: May 7, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–11150 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC677

North Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will hold public meetings, June 3–11, 2013 at the Centennial Hall, 101 Egan Drive, Juneau, AK.

DATES: The Council will begin its plenary session at 8 a.m. on Wednesday, June 5, continuing through Tuesday, June 11, 2013. The Scientific Statistical Committee (SSC) will begin at 8 a.m. on Monday, June 3 and continue through Wednesday, June 5. The Council's Advisory Panel (AP) will begin at 8 a.m. on Tuesday, June 4 and continue through Saturday, June 8. The Ecosystem Committee will meet Tuesday, June 4, 2013, 10 a.m. to 5 p.m., at the Federal Building, 709 W. 9th Street, Sustainable Fisheries conference room, 4th floor, Juneau, AK. The Enforcement Committee will meet Tuesday, June 4, from 1 p.m. to 5 p.m. at the Goldbelt Hotel, 51 Egan Drive, Chilkat Room, Juneau, AK. All meetings are open to the public, except executive sessions.

ADDRESSES: The Council meeting will be held at Centennial Hall, 101 Egan Drive, Juneau, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Avenue, Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: David Witherell, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Council Plenary Session

The agenda for the Council's plenary session will include the following issues. The Council may take appropriate action on any of the issues identified.

1. Executive Director's Report
   - NMFS Management Report (including flow scale discussion paper, update on halibut/sablefish IFQ leasing prohibition, Essential Fish Habitat update)
   - NOAA Enforcement Report
   - ADF&G Report
   - USCG Report
   - USFWS Report
   - Protected Species Report (including Progress report and Biological Opinion (BiOp) analytical approach on Steller Sea Lion (SSL) Environmental Impact Statement (EIS)
2. Bering Sea Aleutian Island (BSAI) Crab: Receive Crab Plan Team report; Set final Overfishing Levels (OFL)/Acceptable Biological Catch (ABC) specifications for 4 stocks.
3. Freezer Longline Issues: Final action on Gulf of Alaska (GOA) Pacific cod sideboards; Industry update on Bering Sea Turbot fishery negotiations.
4. Observer Program: Review first year report; Electronic Monitoring (EM) strategic plan; Review Observer Advisory Committee (OAC) report; Review 3rd Party discussion paper.
5. GOA Salmon Chinook Bycatch: Final action on GOA Chinook salmon bycatch in non-pollock trawl fisheries.
6. GOA Trawl Bycatch: Discussion paper on GOA Trawl Bycatch management/roadmap; Initial review on GOA Trawl Data Collection; Tendering report.
7. Limited Access Privilege Programs (LAPPs) Cost Recovery: Council recommendation on cost recovery programs for American Fishery Act (AFA), Amendment 80, and Community Development Quota (CDQ) groundfish/halibut LAPPs.
8. Bering Sea Canyon: Review updated Alaska Fishery Science Center report; Discussion paper on fishing activities and management.
9. Miscellaneous Issues: Initial review of analysis regarding definition of fishing guide (Council only); Update on Halibut/Sablefish Individual Fishing Quota (IFQ) discussion papers (GOA sablefish pots, sablefish A-share caps); Approve Research Priorities.
10. Staff Tasking: Review Committees and tasking.

The SSC agenda will include the following issues:

1. BS/AI Crab
2. GOA Trawl Data Collection
3. Bering Sea Canyons
4. Approve Research Priorities

The Advisory Panel will address most of the same agenda issues as the Council except B reports. The Agenda is subject to change, and the latest version will be posted at *http://www.alaskafisheries.noaa.gov/npfmc/*.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. 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 Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: May 7, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–11149 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC674

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Monkfish Committee on May 29, 2013 and May 30, 2013 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, May 29, 2013 at 10 a.m. and Thursday, May 30, 2013 at 8:30 a.m.

ADDRESSES: *Meeting address:* The meeting will be held at the Hotel Providence, 139 Mathewson Street, Providence, RI 02903; telephone: (401) 861–8000; fax: (401) 732–9309.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Monkfish Oversight Committee will: (1) Provide an assessment update review; (2) report on the May 16 Scientific and Statistical Committee meeting and recommendations for Allowable Biological Catch (ABC); (3) report on the April 30 Plan Development Team (PDT) meeting; (4) provide a presentation outlining DAS/trip limit options developed by the PDT; (5) discuss and develop recommendations to the New England and Mid-Atlantic Councils for a range of alternatives to be included in Framework 8 including, but not limited to, Annual Catch Targets (ACT—applying management uncertainty to ACL), the range of DAS/trip limit alternatives (specifications), changes to the permit category H fishery boundary and any other options for DAS changes; (6) discuss, including motions, as appropriate, the range of alternatives to be included in the Amendment 6 document, including possible removal of the ITQ alternative; (7) discuss, including development of recommendations, as appropriate, possible revisions to the pending monkfish Emergency Action for the 2013 fishing year; (8) consider and develop a recommendation to the Councils that monkfish permit renewal be required at the start of the fishing year to address state waters fishing; (9) time permitting, consider making recommendations on changes to the Research Set-Aside priorities; (10) closed session to review/recommend Advisory Panel applications.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: May 7, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–11155 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC666

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) Highly Migratory Species Management Team (HMSMT) will hold a meeting, which is open to the public.

DATES: The HMSMT work session will begin at 3 p.m. on Tuesday, May 28; 8:30 a.m. on Wednesday, May 29; and 8:30 a.m. Thursday, May 30, 2013. On each day, the meeting will continue until business is completed.

ADDRESSES: *Meeting address:* The meeting will be held in the Pacific Room, Southwest Fisheries Science Center, 8901 La Jolla Shores Dr., La Jolla, CA 92037–1509.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Dr. Kit Dahl, Pacific Council; telephone: (503) 820–2280.

SUPPLEMENTARY INFORMATION: The HMSMT will discuss the following topics:

1. An assignment from the March 2013 Council meeting in Tacoma, WA. The Council directed the HMSMT to identify potential measures that should be implemented pursuant to the precautionary management framework for North Pacific albacore currently under development at the international level. The HMSMT will provide a report with its recommendations at the June 20–25, 2013, Pacific Council meeting.
2. Response to finding by National Marine Fisheries Service that Pacific bluefin tuna (Thunnus orientalis) is overfished and recommendations for Pacific Council response per Section 304(i) of the Magnuson-Stevens Conservation and Management Act.
3. Work on the 2013 Stock Assessment and Fishery Evaluation document, which is prepared annually, summarizing information from the previous year.
4. Future work planning.
5. Informational topics related to HMSMT responsibilities.

Although non-emergency issues not contained in the meeting agenda may be

discussed, those issues may not be the subject of formal action during these meetings. 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 meetings are 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 at least 5 days prior to the meeting date.

Dated: May 6, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–11083 Filed 5–9–13; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services previously furnished by such agencies.

DATES: *Comments Must Be Received On or Before:* 6/10/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and service are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

NSN: 8970–00–NSH–0026—Meal Kit, Turkey, Detainees, DHS ICE
NSN: 8970–00–NSH–0027—Meal Kit, Roast Beef, Detainees, DHS ICE
NPA: The Arc of Cumberland and Perry Counties, Carlisle, PA
Contracting Activity: DEPT OF HOMELAND SECURITY, U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT, COMPLIANCE AND REMOVALS, WASHINGTON, DC
Coverage: C-List for 100% of the requirement of the U.S. Immigration and Customs Enforcement, York, PA detainment facility, as aggregated by Compliance and Removals, U.S. Immigration and Customs Enforcement, Washington, DC.

Service

Service Type/Location: Custodial Service, Air National Guard Air Force Reserve Command Test Center (AATC), 1600 E. Super Sabre Drive, Bldg. 10, Tucson, AZ.
NPA: Beacon Group SW., Inc., Tucson, AZ
Contracting Activity: DEPT OF THE ARMY, W7MV USPFO ACTIVITY AZ ARNG, PHOENIX, AZ

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

Medium Weight Plastic Cutlery

NSN: 7340–00–NIB–0005
NSN: 7340–00–NIB–0006
NSN: 7340–00–NIB–0007
NSN: 7340–00–NIB–0008
NPA: L.C. Industries for the Blind, Inc., Durham, NC
Contracting Activity: DEPT OF THE ARMY, W40M NATL REGION CONTRACT OFC, FORT BELVOIR, VA

Emergency Administrative Kit

NSN: 7520–00–NIB–1738—50 Person
NPA: Associated Industries for the Blind, Milwaukee, WI
Contracting Activities: GSA/FAS CENTER OF INNOVATIVE ACQUISITION DEV, ARLINGTON, VA
FEDERAL EMERGENCY MANAGEMENT AGENCY (FEMA), NETC ACQUISITION SECTION, WASHINGTON, DC

NSN: 7045–01–484–1764—Mouse Pad w/ Calculator
NPA: MidWest Enterprises for the Blind, Inc., Kalamazoo, MI
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Clock, Wall, Battery

NSN: 6645–01–467–8475
NSN: 6645–01–467–8476

Clock, Atomic, Standard, Thermometer

NSN: 6645–01–491–9806
NSN: 6645–01–491–9816
NSN: 6645–01–491–9824
NSN: 6645–01–491–9827
NSN: 6645–01–491–9836
NSN: 6645–01–499–0892
NSN: 6645–01–499–0893
NSN: 6645–01–499–0894
NSN: 6645–01–499–0896
NSN: 6645–01–492–0900

Clock, Wall, Customized

NSN: 6645–01–456–5010
NSN: 6645–01–456–6035

Clock, Wall

NSN: 6645–01–421–6900
NSN: 6645–01–421–6909

Slimline Wall Clock

NSN: 6645–01–516–9631—12'' Putty Case
NPA: The Chicago Lighthouse for People Who Are Blind or Visually Impaired, Chicago, IL
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Services

Service Type/Location: Grounds Maintenance Service, Fort Sam Houston: Quarters and Common Areas, Fort Sam Houston, TX.
NPA: Goodwill Industries of San Antonio, San Antonio, TX
Contracting Activity: DEPT OF THE ARMY, W40M NATL REGION CONTRACT OFC, FORT BELVOIR, VA

Service Type/Location: Parts Sorting Service, Kelly Air Force Base: Defense Reutilization and Marketing Office, Kelly AFB, TX.
NPA: Goodwill Industries of San Antonio, San Antonio, TX
Contracting Activity: DEPT OF THE AIR FORCE, FA7014 AFDW A7KI, ANDREWS AFB, MD

Service Type/Location: Grounds Maintenance Service, Kelly Air Force Base: Military Family Housing, Kelly AFB, TX.
NPA: Goodwill Industries of San Antonio, San Antonio, TX
Contracting Activity: DEPT OF THE AIR FORCE, FA7014 AFDW A7KI, ANDREWS AFB, MD

Service Type/Location: Laundry Service, Fort Sam Houston/Fort Hood, TX.
NPA: Goodwill Industries of San Antonio, San Antonio, TX
Contracting Activity: DEPT OF THE ARMY, W40M NATL REGION CONTRACT OFC, FORT BELVOIR, VA

Service Type/Location: Recycling Service, Kelly Air Force Base: Basewide, Kelly AFB, TX.
NPA: Goodwill Industries of San Antonio, San Antonio, TX
Contracting Activity: DEPT OF THE AIR FORCE, FA7014 AFDW A7KI,

ANDREWS AFB, MD

Service Type/Location: Linen Service, Fort Hood: Postwide, Fort Hood, TX.

NPA: Goodwill Industries of San Antonio, San Antonio, TX

Contracting Activity: DEPT OF THE ARMY, W40M NATL REGION CONTRACT OFC, FORT BELVOIR, VA

Service Type/Location: Grounds Maintenance Service, Kelly Air Force Base: Basewide (except Military Family Housing), Kelly AFB, TX.

NPA: Training, Rehabilitation, & Development Institute, Inc., San Antonio, TX

Contracting Activity: DEPT OF THE AIR FORCE, FA7014 AFDW A7KI, ANDREWS AFB, MD

Service Type/Location: Petroleum Support Service, Fort Sam Houston/Camp Bullis, TX.

NPA: Goodwill Industries of San Antonio, San Antonio, TX

Contracting Activity: DEPT OF THE ARMY, W40M NATL REGION CONTRACT OFC, FORT BELVOIR, VA

Service Type/Location: Operation of Postal Service Center/BITS Service, Brooks Air Force Base: Base Wide, Brooks AFB, TX.

NPA: Goodwill Industries of San Antonio, San Antonio, TX

Contracting Activity: DEPT OF THE AIR FORCE, FA7014 AFDW A7KI, ANDREWS AFB, MD

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–11156 Filed 5–9–13; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletion from the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes a service from the Procurement List previously furnished by such agency.

DATES: *Effective Date:* 6/10/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 3/1/2013 (78 FR 13868–13869) and 3/8/2013 (78 FR 15000), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

NSN: 7930–00–NIB–0644—Cleaning Pad, Melamine Foam, White, 4″ × 1.5″ × 4″

NPA: West Texas Lighthouse for the Blind, San Angelo, TX

Contracting Activity: General Services Administration, Fort Worth, TX

Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

Shirt, Sleeping

NSN: 8415–00–890–2099

NSN: 8415–00–890–2100

NSN: 8415–00–890–2101

NSN: 8415–00–890–2102

NSN: 8415–00–890–2103

NSN: 8415–00–935–6855

NPA: Mount Rogers Community Services Board, Wytheville, VA

Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

Coverage: C-List for 100% of the requirement of the U.S. Army, as aggregated by the Defense Logistics Agency Troop Support, Philadelphia, PA.

Deletion

On 4/5/2013 (78 FR 20622–20623), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletion from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the service listed below is no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to provide the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service deleted from the Procurement List.

End of Certification

Accordingly, the following service is deleted from the Procurement List:

Service

Service Type/Location: Document Processing Service, Bureau of Alcohol, Tobacco, Firearms & Explosives, National Training Center, 244 Needy Road, Martinsburg, WV.

NPA: Jeanne Bussard Center, Inc., Frederick, MD

Contracting Activity: DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–11157 Filed 5–9–13; 8:45 am]

BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Sunshine Act Meeting

The Board of Directors of the Corporation for National and Community Service gives notice of the following meeting:

DATE AND TIME: Wednesday, May 15, 2013, 9:00–10:30 a.m.

PLACE: Corporation for National and Community Service, 1201 New York Avenue NW., Suite 8312, Washington, DC 20525 (Please go to 10th floor reception area for escort).

CALL-IN INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–889–5014 conference call access code number 5933738. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and CNCS will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Replays are generally available one hour after a call ends. The toll-free phone number for the replay is 866–507–3580, replay passcode 3603. The end replay date is May 29, 2013, 10:59 p.m. (CT).

STATUS: Open.

MATTERS TO BE CONSIDERED:

I. Chair's Opening Comments
  a. Call to Order, Welcome, and Preview of Today's Meeting Agenda
  b. Introduction and Acknowledgements
  c. Summary of Retreat
II. Committee Reports
III. Consideration of Previous Meeting's Minutes
IV. CEO Report
V. Acknowledgement of Board Member Transitions
VI. Discussions, Deliberations and Official Actions
VII. Public Comments
VIII. Final Comments and Adjournment

Members of the public who would like to comment on the business of the Board may do so in writing or in person. Individuals may submit written comments to *jmauk@cns.gov* subject line: MAY 2013 CNCS BOARD MEETING by 4:00 p.m. (ET) on May 10, 2013. Individuals attending the meeting in person who would like to comment will be asked to sign-in upon arrival. Comments are requested to be limited to 2 minutes.

REASONABLE ACCOMMODATIONS: The Corporation for National and Community Service provides reasonable accommodations to individuals with disabilities where appropriate. Anyone who needs an interpreter or other accommodation should notify Ida Green at *igreen@cns.gov* or 202–606–6861 by 5 p.m. (ET) on May 10, 2013.

CONTACT PERSON FOR MORE INFORMATION: Jenny Mauk, Special Assistant to the CEO, Corporation for National and Community Service, 1201 New York Avenue NW., Washington, DC 20525. Phone: (202) 606–6615. Fax: (202) 606–3460. TTY: (800) 833–3722. Email: *jmauk@cns.gov.*

Dated: May 8, 2013.

Valerie Green,

General Counsel.

[FR Doc. 2013–11270 Filed 5–8–13; 4:15 pm]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Secretary of the Navy Advisory Panel

AGENCY: Department of the Navy, DoD.

ACTION: Notice of Open Meeting via Audio Conferencing.

SUMMARY: The Secretary of the Navy (SECNAV) Advisory Panel will discuss recommendations from the Naval Research Advisory Committee on ''How Autonomy can Transform Naval Operations'' and ''Lightening the Information Load''.

DATES: The Audio Conference will be held on May 13, 2013 from 10:00 a.m. to 12:30 p.m.

ADDRESSES: 1000 Navy Pentagon, Washington, DC 20350–1000. Pentagon Conference Room 4B746.

This will be an audio conference. The SECNAV Advisory Panel Staff will have access to one line open to the public, in the conference room 4B746.

Public access is limited due to the Pentagon Security requirements. Any individual wishing to attend or dial into the audio conference should contact LCDR John Halttunen at 703–695–3042 or Captain Peter Brennan at 703–695–3032 no later than May 8, 2013. Members of the public who do not have Pentagon access will be required to also provide Name, Date of Birth and Social Security number by May 8, 2013 in order to obtain a visitor badge. Public transportation is recommended as public parking is not available. Members of the public wishing to attend this event must enter through the Pentagon's Metro Entrance between 9:00 a.m. and 9:30 a.m. where they will need two forms of identification in order to receive a visitors badge and meet their escort. Members will then be escorted to Room 4B746 to attend the open sessions of the Advisory Panel. Members of the Public shall remain with designated escorts at all times while on the Pentagon Reservation. Members of the public will be escorted back to the Pentagon Metro Entrance upon completion of the meeting.

FOR FURTHER INFORMATION CONTACT: Captain Peter Brennan, SECNAV Advisory Panel, 1000 Navy Pentagon, Washington, DC 20350–1000, 703–695–3032.

SUPPLEMENTARY INFORMATION: Individuals or interested groups may submit written statements for consideration by the SECNAV Advisory Panel at any time or in response to the agenda of a scheduled meeting. All requests must be submitted to the Designated Federal Officer at the address detailed below.

If the written statement is in response to the agenda mentioned in this meeting notice then the statement, if it is to be considered by the Panel for this meeting, must be received at least five days prior to the meeting in question.

The Designated Federal Officer will review all timely submissions with the SECNAV Advisory Panel Chairperson, and ensure they are provided to members of the SECNAV Advisory Panel before the meeting that is the subject of this notice.

To contact the Designated Federal Officer, write to: Designated Federal Officer, SECNAV Advisory Panel, 1000 Navy Pentagon, Washington, DC 20350, 703–695–3032.

Dated: May 1, 2013.

D. G. Zimmerman,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2013–11161 Filed 5–9–13; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

U.S. Energy Information Administration

Proposed Change to Data Protection

AGENCY: U.S. Energy Information Administration (EIA), U.S. Department of Energy (DOE).

ACTION: Notice and Request for Review and Comment.

SUMMARY: This notice pertains to Forms EIA–3, the Quarterly Coal Consumption and Quality Report–Manufacturing and Transformation/Processing Coal Plants and Commercial and Institutional Coal Users; EIA–5, the Quarterly Coal Consumption and Quality Report–Coke Plants; EIA–7A, the Coal Production and Preparation Report—Coal Mines and Preparation Plants; and EIA–8A, the Coal Stocks Report–Traders and Brokers. EIA proposes to change and strengthen the data protection provisions on Forms EIA–3, EIA–5, EIA–7A, and EIA–8A.

No changes are proposed for the standby surveys Forms: EIA–1, Weekly Coal Monitoring Report-General Industries and Blast Furnaces; EIA–4, Weekly Coal Monitoring Report-Coke

Plants; EIA–6Q, Quarterly Coal Report-Coal Producers and Distributors; and EIA–20, Weekly Coal Monitoring Report of Coal Burning Utilities and Independent Power Producers.

EIA's initial action was a request for comment(s) from interested parties and those who might be affected by changes in the EIA confidentiality procedure regarding these coal survey forms. The request for comments was widely publicized through a **Federal Register** Notice (FRN), emails to respondents and trade groups, and announcements on the Internet. (Refer to **Federal Register**: November 27, 2012 (Volume 77, No. 228) [pp 70745–70746]. Also, on December 19, 2012, EIA held a webinar with stakeholders, including members of the National Lime Association and National Mining Association, to explain the proposed change in the confidentiality protections and solicit comments. The comments received from the members of the National Lime Association and National Mining Association supported the proposed changes.

In this notice, EIA proposes to protect and withhold from public release company level information reported on Forms EIA–3, EIA–5, EIA–7A, and EIA–8A. Currently, data reported on these forms are not protected except for certain selected cost and revenue data elements. For Forms EIA–3, EIA–5, and EIA–8A, EIA proposes to protect company information reported on these forms from public release in identifiable form to the extent it satisfies exemption criteria under the Freedom of Information Act and the Trade Secrets Act. However, disclosure limitation procedures will not be applied to the State- and regional-level, statistical, and quantity data published from these surveys. Thus, there may be some statistics that are based on data from fewer than three respondents that may affect the identifiability of reported data. Disclosure limitation procedures will be applied to cost data reported on Forms EIA–3 and EIA–5 and revenue data reported on Forms EIA–7A and EIA–8A. With regards to Form EIA–7A only, the name and address of the responding company, the mine or plant type, and location will continue to be considered public information. These data elements will continue to be released in EIA's public use files and will not be protected from disclosure in identifiable form when releasing statistical aggregate (State-level) information. These data elements are currently released on the EIA Web site in the Form EIA–7A public use file, along with company identifiable Mine Safety and Health Administration (MSHA) data, which are also not protected. All other information reported on Form EIA–7A will be protected from public release in identifiable form to the extent it satisfies exemption criteria under the Freedom of Information Act and the Trade Secrets Act. All proposed changes to the data protection provisions for Forms EIA–3, EIA–5, EIA–7A, and EIA–8A will be retroactive and apply to data reported for calendar years 2011 and 2012. Applying this change retroactively to data reported for 2011 preserves the continuity of certain data series and provides continuity for the main components of EIA's pre-2011 data protection policy. Responses to EIA–3, EIA–5, EIA–7A, and EIA–8A are mandatory.

DATES: Comments regarding this collection must be received on or before June 10, 2013. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4718 or contacted by email at *chad_s_whiteman@omb.eop.gov.*

ADDRESSES: Written comments should be sent to Desk Officer for the Department of Energy Office of Information and Regulatory Affairs, Office of Management and Budget New Executive Office Building Room 10102, 735 17th Street NW., Washington, DC 20503.

And to: Attn: Tejasvi Raghuveer, EIA–3 Survey Manager, U.S. Energy Information Administration, EI–24, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Tejasvi Raghuveer at the address listed above in **ADDRESSES**.

SUPPLEMENTARY INFORMATION:

EIA–3: (1) *OMB No.:* 1905–0167; (2) *Information Collection Request Title:* Quarterly Coal Consumption and Quality Report–Manufacturing and Transformation/Processing Coal Plants and Commercial and Institutional Coal Users; (3) *Type of Request:* change to respondent-level protection policy and disclosure limitation procedures; (4) *Purpose:* to collect all data elements from Form EIA–3 respondents, to release or publish data that is not company identifiable, and does not satisfy the criteria for an exemption under the Freedom of Information Act or satisfy the requirements of the Trade Secrets Act; (5) *Estimated Number of Respondents Quarterly:* 498; (6) *Estimated Number of Responses Annually:* 1992; (7) *Estimated Number of Burden Hours Annually:* 2490 hours; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $170,116.80.

EIA–5: (1) *OMB No.:* 1905–0167; (2) *Information Collection Request Title:* Quarterly Coal Consumption and Quality Report–Coke Plants; (3) *Type of Request:* change to respondent-level protection policy and disclosure limitation procedures; (4) *Purpose:* to collect all data elements from Form EIA–5 respondents, to release or publish data that is not company identifiable, and does not satisfy the criteria for an exemption under the Freedom of Information Act or satisfy the requirements of the Trade Secrets Act; (5) *Estimated Number of Respondents Quarterly:* 19; (6) *Estimated Number of Responses Annually:* 76; (7) *Estimated Number of Burden Hours Annually:* 114 hours; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $7,788.48.

EIA–7A: (1) *OMB No.:* 1905–0167; (2) *Information Collection Request Title:* Coal Production and Preparation Report–Coal Mines and Preparation Plants; (3) *Type of Request:* change to respondent-level protection policy and disclosure limitation procedures; (4) *Purpose:* to collect all data elements from Form EIA–7A respondents, to release or publish data considered public information (name and address of the responding company, the mine or plant type, and location), and does not satisfy the criteria for an exemption under the Freedom of Information Act or satisfy the requirements of the Trade Secrets Act; (5) *Estimated Number of Respondents Annually:* 1306; (6) *Estimated Number of Responses Annually:* 1306; (7) *Estimated Number of Burden Hours Annually:* 2350.8; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $160,606.66.

EIA–8A: (1) *OMB No.:* 1905–0167; (2) *Information Collection Request Title:* Coal Stocks Report–Traders and Brokers; (3) *Type of Request:* change to respondent-level protection policy and disclosure limitation procedures; (4) *Purpose:* to collect all data elements from Form EIA–8A respondents, to release or publish data that is not company identifiable, and does not satisfy the criteria for an exemption under the Freedom of Information Act or satisfy the requirements of the Trade Secrets Act; (5) *Estimated Number of Respondents Annually:* 89; (6) *Estimated Number of Responses Annually:* 89; (7) *Estimated Number of Burden Hours Annually:* 89 hours; (8)

Annual Estimated Reporting and Recordkeeping Cost Burden: $6,080.48.

Statutory Authority: 15 U.S.C. 772(b), Section 13(b) of the Federal Energy Administration Act of 1974 (FEA Act), Public Law 93–275.

Issued in Washington, DC, on May 6, 2013.

Renee Miller,

Acting Director, Office of Survey Development and Statistical Integration, U.S. Energy Information Administration.

[FR Doc. 2013–11153 Filed 5–9–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP13–862–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: FOSA Modifications May 2013 Filing to be effective 8/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5062.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–863–000.
Applicants: Big Sandy Pipeline, LLC.
Description: FOSA Modifications May 2013 Filing to be effective 8/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5069.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–864–000.
Applicants: Bobcat Gas Storage.
Description: FOSA Modifications May 2013 Filing to be effective 8/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5074.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–865–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: FOSA Modifications May 2013 Filing to be effective 8/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5075.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–866–000.
Applicants: Ozark Gas Transmission, L.L.C.
Description: FOSA Modifications May 2013 Filing to be effective 8/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5080.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–867–000.
Applicants: Texas Eastern Transmission, LP.
Description: FOSA Modifications May 2013 Filing to be effective 8/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5083.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–868–000.
Applicants: CenterPoint Energy Gas Transmission Comp.
Description: CEGT LLC—2013 Negotiated Rate Filing—May to be effective 5/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5084.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–869–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Amendment to Neg Rate Agmt (Devon 34694–49) to be effective 5/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5085.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–871–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Mid-South Expansion Project Phase 2 Rates to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5107.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–872–000.
Applicants: TC Offshore LLC.
Description: Cashout Surcharge 2013 to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5109.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–873–000.
Applicants: ANR Pipeline Company.
Description: High Injectability to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5131.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–874–000.
Applicants: Portland Natural Gas Transmission System.
Description: Revising Credit Language to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5148.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–875–000.
Applicants: Portland Natural Gas Transmission System.
Description: ROFR—Expansion to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5176.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–876–000.
Applicants: Tres Palacios Gas Storage LLC.
Description: Tres Palacios Gas Storage LLC—Filing of Non-Conforming Service Agreement to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5177.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–877–000.
Applicants: East Cheyenne Gas Storage, LLC.
Description: ECGS Operational Purchases and Sales Report.
Filed Date: 5/1/13.
Accession Number: 20130501–5184.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–878–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: WIC FL&U Filing effective 6/1/13 to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5194.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–879–000.
Applicants: Northern Natural Gas Company.
Description: 20130501 Winter Market Area Fuel to be effective 11/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5196.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–880–000.
Applicants: Gulfstream Natural Gas System, L.L.C.
Description: 2013 GNGS TUP/SBA Filing to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5235.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–881–000.
Applicants: Southeast Supply Header, LLC.
Description: 2013 TUP/SBA Annual Filing.
Filed Date: 5/1/13.
Accession Number: 20130501–5237.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–882–000.
Applicants: Ruby Pipeline, L.L.C.
Description: Firm Transportation Service Agreement Update to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5249.
Comments Due: 5 p.m. ET 5/13/13.

Docket Numbers: RP13–883–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Discounted Overrun to be effective 6/1/2013.
Filed Date: 5/1/13.
Accession Number: 20130501–5259.
Comments Due: 5 p.m. ET 5/13/13.

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.

Filings in Existing Proceedings

Docket Numbers: RP13–584–001.
Applicants: Columbia Gas Transmission, LLC.
Description: Revenue Sharing Report—RP12–1021 & RP13–584.
Filed Date: 5/1/13.
Accession Number: 20130501–5229.
Comments Due: 5 p.m. ET 5/13/13.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–11171 Filed 5–9–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Proposed Agency Information Collection

AGENCY: National Nuclear Security Administration, U.S. Department of Energy.

ACTION: Notice and Request for OMB review and comment.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. This proposed collection would be for use of the American Assured Fuel Supply (AFS). DOE created the AFS, a reserve of low enriched uranium (LEU) to serve as a backup fuel supply for foreign recipients (to be supplied through U.S. persons) or for domestic recipients in the event of a fuel supply disruption. DOE published a Notice of Availability for the AFS on August 18, 2011. DOE now needs to publish an application form to clarify the information that must be provided in a request to access the material in the AFS, as set forth in the Notice of Availability. 76 FR 51357, 51358. This application form is necessary in order for DOE to identify if applicants meet basic requirements for use of the AFS and implement this important nonproliferation initiative.

DATES: Comments regarding this collection must be received on or before June 10, 2013. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4718 or contacted by email at *chad_s_whiteman@omb.eop.gov.*

ADDRESSES: Written comments should be sent to the

DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503.

And to

Richard Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, Tel: 202–586–0589, Fax: 202–586–1348.

FOR FURTHER INFORMATION CONTACT: Richard Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, Tel: 202–586–0589, Fax: 202–586–1348.

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) *OMB No.* {''New''}; (2) *Information Collection Request Title:* The American Assured Fuel Supply Program; (3) *Type of Request:* New; (4) *Purpose:* The U.S. Department of Energy (DOE) created the American Assured Fuel Supply (AFS), a reserve of low enriched uranium (LEU) to serve as a backup fuel supply for foreign recipients (to be supplied through U.S. persons) or for domestic recipients in the event of a fuel supply disruption. DOE is committed to making the AFS available to eligible recipients in the case of supply disruptions in the nuclear fuel market. This effort supports the United States Government's nuclear nonproliferation objectives by supporting civilian nuclear energy development while minimizing proliferation risks. DOE published a Notice of Availability for the AFS on August 18, 2011. DOE now needs to publish an application form to clarify the information that must be provided in a request to access the material in the AFS, as set forth in the Notice of Availability. 76 FR 51357, 51358. This application form is necessary in order for DOE to identify if applicants meet basic requirements for use of the AFS and implement this important nonproliferation initiative; (5) *Annual Estimated Number of Respondents:* 10; (6) *Annual Estimated Number of Total Responses:* 1; (7) *Annual Estimated Number of Burden Hours:* 8; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $1,600.

Statutory Authority: The Secretary of Energy is authorized pursuant to the Atomic Energy Act of 1954, as amended (Pub. L. 83–703, 42 U.S.C. 2011 *et seq.*) and the Nuclear Non-Proliferation Act of 1978 (NNPA) (Pub. L. 95–242, 22 U.S.C. 3201 *et seq.*), which encourage the widespread use of atomic energy for peaceful purposes and authorize the Secretary to enter into and distribute nuclear material in cooperation with other nations where appropriate safeguard measures are in place to ensure the material is properly controlled and used for peaceful purposes. In 2005, DOE set aside a portion of its LEU inventory to be used to support the International Atomic Energy Agency's (IAEA) International Nuclear Fuel Bank (INFB) initiative, which is envisioned as an LEU reserve that will be administered by the IAEA and that will serve as a back-up for global supply disruptions. Congress later appropriated $49,540,000 in the Consolidated Appropriations Act, 2008 (Pub. L. 110–161) to fund a portion of the INFB. Congress, in the Explanatory Statement accompanying the House Appropriations Committee Print (which in this Act was given the same effect as a joint explanatory statement), noted that the INFB freed up DOE's LEU set-aside, and recommended DOE also ''allow U.S. interests to purchase uranium fuel from the Reliable Fuel Supply [now the AFS] in the event of supply disruption.'' (H. Approp. Cmte. Print at 592.)

The sale of LEU from the AFS will be conducted consistent with applicable law, the policies and guidance in the ''Secretary of Energy's 2008 Policy Statement on Management of Department of Energy's Excess Uranium Inventory'' (March 11, 2008), and the DOE Excess Uranium Inventory Management Plan.

Issued in Washington, DC, on May 6, 2013.

Anne Harrington,

Principal Deputy Administrator, Defense Nuclear Nonproliferation, National Nuclear Security Administration, U.S. Department of Energy.

[FR Doc. 2013–11154 Filed 5–9–13; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9009–1]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 04/29/2013 through 05/03/2013.

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

SUPPLEMENTARY INFORMATION:

Due to EPA's agency-wide furlough day on Friday, May 24th and the Federal holiday on Monday, May 27th, all EISs must be filed with EPA by Thursday, May 23rd by 5:00 p.m. eastern time for publication under a Notice of Availability in the **Federal Register** for Friday, May 31st.

EIS No. 20130123, Draft Supplement, NRC, PA, GENERIC—License Renewal of Nuclear Plants, Supplement 49, Regarding Limerick Generating Station Units 1 and 2, Comment Period Ends: 06/27/2013, Contact: Leslie Perkins 301–415–2375.

EIS No. 20130124, Draft EIS, DOE, LA, Lake Charles Carbon Capture and Sequestration Project, Comment Period Ends: 06/24/2013, Contact: Pierina Fayish 412–386–5428.

Amended Notices

EIS No. 20130062, Draft EIS, USFS, NM, Roca Honda Mine Project, Exploration and Mine Development, Cibola National Forest, Comment Period Ends: 06/13/2013, Contact: Diane Tafoya 505–346–3809.

Revision to FR Notice Published 03/15/2013; Extending Comment Period from 5/14/2013 to 06/13/2013.

Dated: May 7, 2013.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2013–11189 Filed 5–9–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9812–6]

Workshop To Review Initial Draft Materials for the Nitrogen Oxides (NO_X) Integrated Science Assessment (ISA) for Health Effects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Workshop.

SUMMARY: As part of the review of the air quality criteria for nitrogen oxides (NO_X) and primary (health-based) National Ambient Air Quality Standards (NAAQS) for nitrogen dioxide (NO_2), EPA is announcing a workshop to evaluate preliminary draft materials that will inform the development of the NO_X Integrated Science Assessment (ISA) for health effects. The workshop is being organized by EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development and will be held on June 11, 2013, in Research Triangle Park, North Carolina and will be open to attendance by interested public observers on a first-come, first-served basis up to the limits of available space.

DATES: The workshop will be held on June 11, 2013, beginning at 9:30 a.m. and ending at 5:00 p.m.

ADDRESSES: The workshop will be held in the auditorium of EPA's main campus, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina.

FOR FURTHER INFORMATION CONTACT: Questions regarding information, registration, and logistics for the workshop should be directed to Ms. Brianna Young, telephone: 919–541–9765; facsimile: 919–541–1818; email: *young.brianna@epa.gov.* Questions regarding the scientific and technical aspects of the workshop should be directed to Dr. Molini Patel, telephone: 919–541–1492; facsimile: 919–541–1818; email: *patel.molini@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of Information About the Workshop

Section 109(d) of the Clean Air Act (CAA) requires the U.S. EPA to conduct periodic reviews of the air quality criteria for each air pollutant listed under section 108 of the Act. Based on such reviews, EPA is to retain or revise the NAAQS for a given pollutant as appropriate. As part of these reviews, NCEA assesses newly available scientific information and develops ISA documents (formerly known as Air Quality Criteria Documents) that provide the scientific basis for the reviews of the NAAQS.

NCEA-Research Triangle Park is holding this workshop to inform the Agency's evaluation of the scientific evidence for the review of the primary NAAQS for NO_2. Section 109(b)(1) of the CAA defines primary NAAQS as standards, ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' EPA intends to develop a separate ISA, and NAAQS review, for the secondary (welfare-based) NAAQS for NO_2, in conjunction with a review of the secondary NAAQS for sulfur dioxide. The purpose of the workshop is to obtain review of the scientific content of preliminary draft materials that will inform the development of the draft health effects ISA. Workshop sessions will include review and discussion of preliminary draft materials on the atmospheric chemistry of and human exposure to NO_X as well as health effects evidence from in vivo and in vitro animal toxicology, human clinical, and epidemiology studies. In addition, roundtable discussions will help identify key studies or concepts within each discipline to assist EPA in integrating relevant literature within and across disciplines. These preliminary materials are not being released as an external draft but will be used to guide workshop discussions and inform the development of the draft health effects ISA. This workshop is planned to help ensure that the ISA, once developed, is up-to-date and focuses on the key evidence to inform the scientific understanding for the review of the primary NAAQS for NO_X. EPA is planning to release the first external review draft health effects ISA for NO_X for review by the Clean Air Scientific Advisory Committee and the public in August 2013.

II. Workshop Information

Members of the public may attend the workshop as observers. Space is limited, and reservations will be accepted on a first-come, first-served basis.

Dated: March 1, 2013.

Debra B. Walsh,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2013–11198 Filed 5–9–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9811–2]

Standards of Performance for New Stationary Sources, National Emission Standards for Hazardous Air Pollutants, and the Stratospheric Ozone Protection Program: Recent Posting to the Applicability Determination Index (ADI) Database System of Agency Applicability Determinations, Alternative Monitoring Decisions, and Regulatory Interpretations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces applicability determinations, alternative monitoring decisions, and regulatory interpretations that EPA has made under the New Source Performance Standards (NSPS); the National Emission Standards for Hazardous Air Pollutants (NESHAP); and/or the Stratospheric Ozone Protection Program.

FOR FURTHER INFORMATION CONTACT: An electronic copy of each complete document posted on the Applicability Determination Index (ADI) database system is available on the Internet through the Office of Enforcement and Compliance Assurance (OECA) Web site at: *http://www.epa.gov/compliance/monitoring/programs/caa/adi.html*. The letters and memoranda on the ADI may be located by control number, date, author, subpart, or subject search. For questions about the ADI or this notice, contact Maria Malave at EPA by phone at: (202) 564–7027, or by email at: *malave.maria@epa.gov*. For technical questions about individual applicability determinations or monitoring decisions, refer to the contact person identified in the individual documents, or in the absence of a contact person, refer to the author of the document.

SUPPLEMENTARY INFORMATION:

Background

The General Provisions of the NSPS in 40 Code of Federal Regulations (CFR) part 60 and the General Provisions of the NESHAP in 40 CFR part 61 provide that a source owner or operator may request a determination of whether certain intended actions constitute the commencement of construction, reconstruction, or modification. EPA's written responses to these inquiries are commonly referred to as applicability determinations. See 40 CFR 60.5 and 61.06. Although the NESHAP part 63 regulations [which include Maximum Achievable Control Technology (MACT) standards] and § 111(d) of the Clean Air Act (CAA) contain no specific regulatory provision providing that sources may request applicability determinations, EPA also responds to written inquiries regarding applicability for the part 63 and § 111(d) programs. The NSPS and NESHAP also allow sources to seek permission to use monitoring or recordkeeping that is different from the promulgated requirements. See 40 CFR 60.13(i), 61.14(g), 63.8(b)(1), 63.8(f), and 63.10(f). EPA's written responses to these inquiries are commonly referred to as alternative monitoring decisions. Furthermore, EPA responds to written inquiries about the broad range of NSPS and NESHAP regulatory requirements as they pertain to a whole source category. These inquiries may pertain, for example, to the type of sources to which the regulation applies, or to the testing, monitoring, recordkeeping, or reporting requirements contained in the regulation. EPA's written responses to these inquiries are commonly referred to as regulatory interpretations. EPA currently compiles EPA-issued NSPS and NESHAP applicability determinations, alternative monitoring decisions, and regulatory interpretations, and posts them to the ADI on a quarterly basis. In addition, the ADI contains EPA-issued responses to requests pursuant to the stratospheric ozone regulations, contained in 40 CFR part 82. The ADI is an electronic index on the Internet with over one thousand EPA letters and memoranda pertaining to the applicability, monitoring, recordkeeping, and reporting requirements of the NSPS, NESHAP, and stratospheric ozone regulations. Users can search for letters and memoranda by date, office of issuance, subpart, citation, control number, or by string word searches.

Today's notice comprises a summary of 63 such documents added to the ADI on March XX, 2013. This notice lists the subject and header of each letter and memorandum, as well as a brief abstract of the letter or memorandum. Complete copies of these documents may be obtained from the ADI through the OECA Web site at: *www.epa.gov/compliance/monitoring/programs/caa/adi.html*

Summary of Headers and Abstracts

The following table identifies the database control number for each document posted on the ADI database system on March XX, 2013; the applicable category; the section(s) and/or subpart(s) of 40 CFR part 60, 61, or 63 (as applicable) addressed in the document; and the title of the document, which provides a brief description of the subject matter.

We have also included an abstract of each document identified with its control number after the table. These abstracts are provided solely to alert the public to possible items of interest and are not intended as substitutes for the full text of the documents. This notice does not change the status of any document with respect to whether it is ''of nationwide scope or effect'' for purposes of CAA § 307(b)(1) For example, this notice does not convert an applicability determination for a particular source into a nationwide rule. Neither does it purport to make a previously non-binding document binding.

ADI DETERMINATIONS UPLOADED ON MARCH XX, 2013

Control No.	Categories	Subparts	Title
M120002	MACT	LLL	Performance Test Frequency Waiver Request.
M120003	MACT	RRR	Performance Test Waiver Request—Group 1 Furnace.
M120005	MACT	DDDD	Request For Routine Control Device Maintenance Exemption.
M120006	MACT	DDDD	Performance Test Waiver Requests.
M120007	MACT, NESHAP	HH, V	Alternative Monitoring Plan For Ethylene Glycol Service.
M120008	NSPS, MACT	J, UUU	Alternative Monitoring Plan For Opacity at Fluid Catalytic Cracking Units.
1200005	NSPS	H	Alternative Monitoring Plan for Opacity at—Sulfuric Acid Plant.
1200006	NSPS	A, J	Alternate Span Values for Sulfur Dioxide Continuous Emission Monitoring Systems.
1200016	NSPS	J	Alternative Monitoring Plan for Platformer Regeneration Process.

ADI DETERMINATIONS UPLOADED ON MARCH XX, 2013—Continued

Control No.	Categories	Subparts	Title
1200017	NSPS	J	Alternative Monitoring Plan for Refining Tank Truck Loading Rack Vent Stream.
1200018	NSPS	J	Alternative Monitoring Plan for Hydrogen Sulfide in Refining-Wastewater API Separator Off-Gas Vent Stream.
M120010	MACT	NNNNN	Alternative Monitoring Plan For pH for Water Absorbers at Aqueous Hydrochloric Acid Production.
M120011	MACT	NNNNN	Modification of an Approved Alternative Monitoring Plan For Caustic Scrubber.
1200019	NSPS	NNN, RRR	Alternative Monitoring Plan for Vent Stream Flow Monitoring Requirements at Distillation Columns—Implementing Provisions of NSPS Subpart RRR in Lieu of Subpart NNN.
1200020	NSPS	NNN, RRR	Alternative Monitoring Plan for Vent Steam Flow Monitoring Requirements at Distillation Columns—Implementing Provisions of NSPS Subpart RRR in Lieu of Subpart NNN.
1200021	NSPS	NNN, RRR	Modification to an Approved Alternative Monitoring Plan for Vent Stream Flow Monitoring Requirements at Distillation Columns—Implementing Provisions of NSPS Subpart RRR in Lieu of Subpart NNN.
M120014	NSPS, MACT	J, UUU	Modification of an Approved Alternative Monitoring Plan For Opacity at Fluid Catalytic Cracking Units.
Z120002	NESHAP	FF	Wastewater Upstream of Sour Water Stripper.
1200026	NSPS	J	Alternative Monitoring Plan For Opacity at Fluid Catalytic Cracking Units.
M120016	MACT	TTTTTT	Performance Testing Waiver for an Identical Process Control Equipment.
1200029	NSPS	NNN	Flow Monitoring Requirements—Alternate Control Devices Under Subpart NNN.
1200034	NSPS	CCCC	Applicability to a Thermal Desorption System for the Treatment of Diesel Contaminated Drill Cuttings from Deep Natural Gas Wells.
1200035	NSPS	D	Alternative Monitoring Plan for Opacity.
M120019	MACT	S	Alternate Monitoring Plan for Condensate Treatment.
1200036	NSPS	D	Alternative Monitoring Plan for Opacity.
1200037	NSPS	NNN, RRR	Alternative Monitoring Plan-Flow Monitoring Requirements for Vent Stream at Distillation Column—Implementing Provisions of NSPS Subpart RRR in Lieu of Subpart NNN.
1200045	NSPS	A, UUU	Applicability to Kaolin Processing and Catalyst Production.
1200050	NSPS	Y	Applicability to Mechanical Vents on Buildings.
1200051	NSPS	Dc	Applicability to Boiler Derate.
1200054	NSPS	WWW	Request for Alternative Compliance Remedy/Schedule for Landfill Methane Surface Emissions.
1200055	NSPS	WWW	Request for Alternative Compliance Remedy/Schedule for Landfill Methane Surface Emissions.
1200060	NSPS, NESHAP	J, UUU	Alternative Monitoring Plan for Opacity Monitoring System.
1200061	NSPS	A	Alternate RATA Protocol in Relation to Flares Vent Streams—Withdrawal of Previous Approval.
1200063	NSPS	Kb	Requirements for Degassing and Inspecting Floating Roof Tanks.
M120022	MACT	DDDDD	Site-specific Fuel Analysis for Utility Boiler.
1200065	NSPS	J	Low-Sulfur Rule Exemption Approval Supersedes Refinery Approved Alternative Monitoring Plan for Hot Oil Drum Off-Gas Vent Stream.
1200066	NSPS	J	Low-Sulfur Rule Exemption Approval Supersedes Refinery Approved Alternative Monitoring Plan—for Knock-out Drum Off-Gas Vent Stream.
1200067	NSPS	J	Low-Sulfur Rule Exemption Approval Supersedes Refinery Alternative Monitoring Plan for a Caustic Oxidation Unit Off-Gas Vent Stream.
1200068	NSPS	J	Low-Sulfur Rule Exemption Approval Supersedes Refinery Approved Alternative Monitoring Plan for Loading Racks Off-Gas Vent Streams.
1200069	NSPS	J	Low-Sulfur Rule Exemption Approval Supersedes Refinery Approved Refinery Alternative Monitoring Plan for a Benzene Recovery Unit Off-Gas Vent Stream.
1200070	NSPS	J	Low-Sulfur Rule Exemption Approval Supersedes Refinery Approved Alternative Monitoring Plan—for Refinery Marine Vessel Loading Vapors.
M120023	MACT	BBBBBB	Applicability of Rule to Storage and Transfer of Transmix.
1200071	NSPS	J	Low Sulfur Rule Exemption for Process Unit Vent Streams Combusted in Flare.
M120024	MACT, NSPS	CC, G, Kb	Request for Interpretation of Recordkeeping Requirements as Applied to Storage Tanks Inspections.
1200072	NSPS	J	Alternative Monitoring Plan Request for a Refinery Flare 2.
1200073	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Truck and Railcar Loading Vent Off-Gas Stream.
1200076	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Vent Streams.
1200077	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Refinery Pit Collection Header Vent Stream.
1200078	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Refinery Storage Tank and Loading Arm Vent Streams.
1200079	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Refinery Pit and Loading Arm Vent Streams.
1200081	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Refinery Pressure Swing Absorber Vent Stream.
1200084	NSPS	UUU	Alternative Monitoring Request For Proposed Kilns.
1200085	NSPS	UUU	Applicability to Mixer/Dryer Processing a Very Wet Alumina Slurry.

ADI DETERMINATIONS UPLOADED ON MARCH XX, 2013—Continued

Control No.	Categories	Subparts	Title
M120025	MACT	JJJJ	Alternative Monitoring Request to Meet Calibration Verification Requirements for Catalytic Oxidizers.
M120028	MACT, NSPS	A, A, CC	Alternative Monitoring Request of Acoustic Flare Pilot Flame at Utility Flare.
M120030	MACT	WWWWWW	Applicability to Chrome Etching Process Meeting Definition of Electropolishing.
1200089	NSPS	J	Low Sulfur Rule Exemption Approval Supersedes Alternative Monitoring Plan for Refinery Pit Collection Header Vent Stream.
M120031	MACT	UUUU	Categorization of Coal-Fired Utility Steam Engines.
M120032	MACT	RRR	Applicability to Secondary Aluminum Production Furnace Switching Operating Category From Group 1 to Group 2.
1200091	NSPS	AAA	Regulatory Interpretation on Wood Heater Remote Certification Testing.
Z120004	MACT, NESHAP	ZZZZ	RICE NESHAP One-Year Compliance Extension for Diesel Engines.
1200092	NSPS	IIII	National Security Exemption for Non-Road Diesel Engines at Air Force Base.
WDS–145	Woodstoves		Canadian Standards Administration B415.1 Alternative Test Method Request for Generating Thermal Efficiency Ratings.

Abstracts

Abstract for [M120002]

Q1: Does EPA approve Alamo Cement Company's (Alamo) waiver request of the next performance test for monitoring of dioxin/furans (D/F) at the Alamo facility located in San Antonio, Texas, since similar requests have been approved for other facilities?

A1: No. EPA does not approve Alamo's performance test waiver request based upon the facility's specific circumstances. EPA notes that applicability determinations are site-specific and are decided on a case-by-case basis.

Q2: Does EPA approve a waiver for less frequent testing, at five-year intervals instead of the 30-month interval required by 40 CFR 63.1349(d) of NESHAP subpart LLL, based on economic impracticality of the frequency of testing and consideration of previous performance test data demonstrating high performance compliance?

A2: No. The EPA does not approve conducting performance tests for dioxin/furans at a frequency less than the 30-month interval required under the final rule. This frequency is necessary to determine actual D/F levels and assess compliance. The emission testing is also necessary to establish operating temperature limits.

Abstract for [M120003]

Q1: Does EPA approve a waiver for a 90-day time extension for conducting a performance test, required under NESHAP MACT 40 CFR part 63 subpart RRR, at the Alumax Mill Products facility (Alumax), located in Texarkana, Texas based on availability of scrap and changes in ambient temperature only?

A1: No. EPA does not approve Alumax's request for a 90-day time extension to conduct performance testing in accordance with 40 CFR part 63 subpart RRR at the Texarkana facility, as the rationale provided does not justify its approval. Alumax should have been able to obtain sufficient amounts of the type of scrap normally melted in the furnaces to be able to test prior to the May 2009 deadline. Also, any change in ambient temperatures between May and August should have minimal effect on the inlet temperatures at the lime-injected fabric filters, since the temperatures are measured after the furnaces.

Abstract for [M120005]

Q1: Does EPA approve a routine control device maintenance exemption (RCDME) under 40 CFR part 63 subpart DDDD, at the Boise Florien Plywood Plant (Boise) in Florien, Louisiana?

A1: Yes. EPA approves a RCDME for Boise under NESHAP subpart DDDD based on the specific information submitted to justify the request, as explained in the EPA response letter, and it being submitted 30 days before the compliance date of October 1, 2007, for NESHAP subpart DDDD. The approved RCDME must be incorporated by reference and attached to the facility's Title V permit.

Abstract for [M120006]

Q1: Does EPA approve a performance test waiver for existing regenerative thermal oxidizers (RTO) at Boise Florien and Oakdale Plywood Plants (Boise) in Louisiana subject to MACT subpart DDDD?

A1: Yes. EPA approves the performance test waiver for the RTOs pursuant to 40 CFR 63.7(2)(e)(iv) and 63.7(h)(2) of the General Provisions. Based upon the information submitted, EPA determined that the 2003 performance tests satisfy the MACT requirements.

Abstract for [M120007]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) consisting of quarterly visual inspections of ancillary equipment in the cooling jacket water service, addressing a mixture of ethylene glycol and water, in lieu of conducting EPA Reference Method 21 field analyzer measurements for BP America Production Company Compressor Station in Sunray, Texas, subject to NESHAP subpart HH?

A1: Yes. EPA approves the AMP for ancillary equipment for the cooling jacket water service at the Sunray Compressor Station. The request is justified since it is difficult to obtain a reproducible and useful response factor as required in Method 21 due to ethylene glycol's low volatility (vapor pressure 0.06 mm Hg at 20 degrees C), as described in EPA report EPA–453/R–95–017, Protocol for Equipment Leak Emission Estimates. It is an acceptable alternative monitoring to meet NESHAP subpart HH requirements since visual evidence of ethylene glycol liquid on or dripping from the equipment would indicate an equipment leak, and repair would be conducted to meet requirements of NESHAP part 61, subpart V.

Abstract for [M120008]

Q1: Will EPA modify the prior approved alternative monitoring plan (AMP), pertaining to the use of parametric monitoring of the Fluid Catalytic Cracking Unit (FCCU) Wet Gas Scrubber (WGS) in lieu of monitoring opacity via continuous opacity monitoring system (COMS), due to moisture interference on opacity readings in the stack for the Chalmette Refining facility in Louisiana?

A1: Yes. EPA will conditionally approve a modified AMP to incorporate changes necessary, due to the physical changes to occur in accordance with the

consent decree. However, a new performance test is necessary to establish new Operating Parameter Limits (OPLs) for the WGS. The performance test will be conducted at representative operating conditions for the FCCU Regenerator and WGS, whereby worst-case emissions are anticipated.

Q2: Will EPA consider further adjustment to the OPLs for the scrubber due to turndown operations, where the gas flow rate from the FCCU Regenerator to the WGS decreases?

A2: Yes. EPA will consider setting OPLs that will account for turndown operations decreased gas flow. OPLs will be set based upon performance test results.

Abstract for [1200005]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for conducting alternate opacity measurements during maintenance flushing of a sulfur dioxide (SO_2) wet scrubber at Chemtrade's Sulfuric Acid Plant located in Tulsa, Oklahoma, subject to NSPS subpart H?

A1: No. EPA does not approve the proposed AMP to monitor sulfuric acid concentration during scrubber flushing, and to conduct Method 9 opacity readings if the COMS showed measurements above 10 percent. Under 40 CFR 60.83, emissions that ''exhibit 10 percent opacity, or greater'' are considered a violation. In addition, Chemtrade did not provide the necessary process unit and scrubber operating data to establish a direct correlation of production process acid concentrations to opacity readings at the scrubber stack. This decision does not preclude Chemtrade from considering the provision of 40 CFR 60.11(e)(8) to pursue approval of an alternative opacity limitation during scrubber flushing via performance testing. To establish an appropriate alternate opacity standard for the scrubber during flushing, a performance test would include mass emission rate determinations for SO_2 and acid mist during typical operation and during scrubber flushing to demonstrate compliance with NSPS subpart H emission standards at all times.

Abstract for [1200006]

Q1: Does EPA approve an alternate span value for a sulfur dioxide (SO_2) continuous emissions monitoring system (CEMS) for wet gas scrubbers (WGS) on a fluidized catalytic cracking unit (FCCU) at the CITGO Petroleum Corporation refinery at Lake Charles in Louisiana, subject to NSPS Subparts A and J?

A1: Yes. EPA, in coordination with Louisiana Department of Environmental Quality, conditionally approves the change of each FCCU WGS Sulfur Dioxide ($S0_2$) CEMS span value from 600 to 100 ppmv, for the CITGO's Lake Charles Refinery. This alternative is acceptable because Citgo determined that the actual, lower outlet SO_2 concentrations at the FCCU WGSs would warrant a reduction of the span value to 100 ppmvd, so that the SO_2 CEMS could pass the annual relative accuracy test audits (RATA) required by NSPS Subpart A Appendix F. Citgo will comply with 40 CFR 60.1 04(b Xl) of NSPS subpart J by maintaining emissions to the atmosphere from the outlet (stack) of each FCCU's wet gas scrubber (WGS) below 50 parts per million by volume (ppmv). This and other conditions for the AMP approval are specified in the EPA response letter.

Abstract for [1200016]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for monitoring hydrogen sulfide (H_2S) in lieu of installing a continuous emission monitoring system (CEMS) for the Platformer Regeneration Process vent stream at the Delek Refining plant located in Tyler, Texas, subject to NSPS subpart J?

A1: Yes. EPA conditionally approves the AMP for the off-gas vent stream from the Platformer Regenerator that is vented to a hydrochloric acid (HCl) scrubber, and then routed to the burners in the heater. The vent stream is inherently low in sulfur content due to the feed stream characteristics and operational controls used in the Platformer Regenerator Process. The parametric monitoring conditions for AMP approval are specified in the EPA response letter.

Abstract for [1200017]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for monitoring hydrogen sulfide (H_2S) in lieu of installing a continuous emission monitoring system (CEMS) at the Delek Refining Tank Truck Loading Rack Flare at the Tyler, Texas refinery, subject to NSPS subpart J?

A1: Yes. EPA conditionally approves the AMP for the Tank Truck Loading Rack off-gas vent stream. In accordance with EPA's Alternative Monitoring Plan for NSPS subpart J Refinery Fuel Gas Guidance, Delek provided data and information that demonstrated the vent stream is inherently low in sulfur content. Delek does not anticipate any new product specifications with sulfur content higher than the ranges provided to EPA in their AMP submittal. The EPA response letter specifies the parametric monitoring conditions for AMP approval.

Abstract for [1200018]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for monitoring hydrogen sulfide (H_2S) in lieu of installing a continuous emission monitoring system (CEMS) for Wastewater API Separator Unit Operations off-gas vent streams that are combusted in the wastewater API separator flare at the Delek Refining facility in Tyler, Texas, subject to NSPS subpart J?

A1: No. EPA does not approve Delek's proposed AMP for the off-gas vent streams from the Wastewater API separator Unit Operations. Delek's proposed AMP does not meet the AMP requirements under NSPS subpart J–Refinery Fuel Gas Guidance. Delek did not provide the necessary data and information to justify the AMP request. Specifically, Delek did not provide a correlation between inherently low and stable H_2S content in the exhaust gas steam in relation to those process parameters proposed in the AMP for the treated wastewater streams. Piping and instrumentation drawings were not provided, as requested, to differentiate between the various wastewater streams and to show specific sampling points being utilized and proposed. Additionally, Delek did not provide the information for all process parameters monitored for the various process units to ensure inherently low and stable H_2S content of the off-gas vent stream to be combusted at the flare. The high target levels of measured H_2S in the wastewater were excessive for consideration of an AMP for the off-gas vent stream.

Abstract for [M120010]

Q1: Does EPA approve a waiver to monitor only the liquid flow rate and not pH through absorbers used to control hydrochloric acid (HCl) emissions at the Dow Chemical Company Aqueous Hydrochloric Acid Production facility in Freeport, Texas, subject to MACT subpart NNNNN?

A1: No. EPA disapproves the waiver request based on insufficient evidence to demonstrate that monitoring liquid flow alone is sufficient to determine the effectiveness of the absorbers. EPA believes that more than one parameter should be monitored to provide a more complete determination of control performance. For example, corrosion or erosion of the spray nozzles and channeling within the packing could affect gas-liquid distribution within an absorber, which decreases its efficiency,

yet may not result in a decrease in the liquid flow rate. In such instances, where the absorber is operating less efficiently and only liquid flow rate is monitored, it is possible to exceed the emission standard while still demonstrating compliance by meeting the minimum flow rate.

Abstract for [M120011]

Q1: Does EPA approve a modification of an Alternative Monitoring Plan (AMP) to remove the 3 percent upper caustic concentration operating limit parameter (OPL) on a scrubber used to control hydrochloric acid (HCl) emissions at the Dow Chemical Company mercaptan derivative process located in Freeport (Dow Freeport), Texas, subject to MACT subpart NNNNN?

A1: Yes. EPA conditionally approves modification of the AMP that allows a waiver of the 3 percent upper caustic concentration limit for the Dow Freeport mercaptan derivative process. EPA agrees that it is unnecessary to maintain an upper limit for caustic concentration to demonstrate compliance, as more caustic concentration would provide greater potential to reduce HCl emissions. Therefore, the waiver is approved as long as the scrubber recirculation caustic concentration is at a minimum of 1.6 percent of sodium hydroxide and the minimum flow rate is at 45 gallons per minute.

Abstract for [1200019]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for vent stream flow monitoring for specific distillation columns and associated flares used as a control device to implement NSPS subpart RRR testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN, with the exception of small vent and drain valves utilized for maintenance events, for Equistar Chemicals facility (Equistar), Channelview Chemical Complex, located in Texas?

A1: Yes. EPA conditionally approves the Equistar AMP request to implement NSPS subpart RRR for testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN for specific distillation columns vent streams routed to unit flares without any by-pass lines. In order to ensure that affected vent streams are routed to appropriate control devices, Equistar Channelview Chemical Complex is required to maintain a schematic diagram of the affected vent streams, collection system(s), fuel systems, control devices, and bypass systems as part of the initial report submitted in accordance with 40 CFR section 60.705(b) of subpart RRR. EPA noted in its approval that the small vent and drain valves utilized by Equistar Channelview Chemical Complex for maintenance events are not an exception under either NSPS subpart NNN or NSPS Subpart RRR. Therefore, flow must be monitored during maintenance events at these locations in accordance with NSPS subpart RRR, because such components act as bypass valves during such events (i.e., flow is diverted away from the control device).

Abstract for [1200020]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for vent stream flow monitoring for specific distillation columns and associated flares to implement NSPS subpart RRR testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN, with the exception of small vent and drain valves utilized for maintenance events, for Equistar Chemicals (Equistar) at the LaPorte Chemical Complex, located in Texas?

A1: Yes. EPA conditionally approves the Equistar AMP request to implement NSPS subpart RRR for testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN for specific distillation columns vent streams routed to unit flares without any by-pass lines. In order to ensure that affected vent streams are routed to appropriate control devices, Equistar LaPorte Chemical Complex facility is required to maintain a schematic diagram of the affected vent streams, collection system(s), fuel systems, control devices, and bypass systems as part of the initial report submitted in accordance with 40 CFR 60.705(b) of subpart RRR. EPA noted in its approval that the small vent and drain valves utilized by Equistar for maintenance events are not an exception under either NSPS subpart NNN or subpart RRR. Therefore, flow must be monitored during maintenance events at these locations in accordance with NSPS subpart RRR, because such components act as bypass valves during such events (i.e., flow is diverted away from the control device).

Abstract for [1200021]

Q1: Does EPA approve modifications to an Alternative Monitoring Plan (AMP) for a distillation column and associated flare to add flexibility of routing vent streams to other control equipment as backup to the flare (i.e., incinerator, boiler or process heater), and to implement NSPS subpart RRR testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN for compliance with both subparts, for Equistar Chemicals (Equistar) at the LaPorte Chemical Complex, located in Texas?

A1: Yes. EPA conditionally approves the Equistar AMP request to modify an approved AMP for testing, monitoring, and recordkeeping provisions in NSPS subpart RRR in lieu of complying with corresponding provisions of NSPS subpart NNN for specific distillation columns vent streams when routed to unit flares and other backup control devices to the flare at the Equistar LaPorte Chemical Complex. The conditions of the original AMP approval also still apply and are specified in the EPA response letter.

Abstract for [M120014]

Q1: Does EPA approve modifying a prior approved Alternative Monitoring Plan (AMP), pertaining to parametric monitoring of the fluid catalytic cracking unit (FCCU) No. 3 wet gas scrubber (WGS) in lieu of monitoring opacity via continuous opacity monitoring system (COMS), due to moisture interference on opacity readings in the stack, at the Exon Mobil Refinery located in Baytown, Texas? Modification is necessary in order to allow nominal flow to a bypass stack during CO Boilers maintenance prior to plant turnaround.

A1: Yes. EPA will conditionally approve a modified AMP to allow nominal flow to the Bypass stack for the 4-month period necessary for maintenance on two of three CO Boilers. The plant turnaround is removing the Bypass Stack and the modified AMP will incorporate this temporary alteration for two of the three boilers. However, due to the number of other requested modifications to the prior approved AMP, EPA will address multiple issues associated with the prior approved AMP for both the FCCU No. 2 and the FCCU No. 3 WGS units. A new performance test is necessary to establish new Operating Parameter Limits (OPLs) for the WGS. Details pertaining to the modified AMP are included in the enclosure of the EPA response letter.

Abstract for [Z120002]

Q1: Are sour water streams managed upstream of a refinery sour water stripper at the Flint Hills Resources (FHR) East Refinery in Corpus Christi, Texas, subject to the Benzene Waste Operations NESHAP (BWOP), subpart FF?

A1: Yes. The application of 40 CFR 61.355 in NESHAP subpart FF does not change the point of generation, but rather changes the location where the owner or operator measures the benzene quantity of sour water streams for the purpose of determining the total annual benzene quantity from the facility. EPA determined that the FHR East Refinery must comply with the requirements of 40 CFR 61.342(c)–(h) for sour water streams managed upstream of a sour water stripper exit, based on the characteristics of the waste streams at their points of generation, assuming the facility's total annual benzene is calculated to be 10 megagrams per year (MG/yr) or greater, and the waste stream does not meet one of the exemptions of 40 CFR 61.340(c)–(d).

Abstract for [1200026]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for wet gas scrubber (WGS) parametric monitoring in lieu of a continuous opacity monitoring system (COMS) on a fluidized catalytic cracking unit (FCCU) covered under NSPS subpart J for the Flint Hills Resources (FHR) facility located at the Corpus Christi complex, in Texas?

A1: Yes. Based on the particular WGS design, the process specific parameters chosen, and the performance test data, EPA approves the AMP to allow that no COM need be installed for the purpose of monitoring the opacity at the West Refinery FCCU flue gas scrubber exit. Instead, the parameters as detailed in the EPA response letter will be monitored and recorded.

Abstract for [M120016]

Q1: Does EPA approve a performance test waiver specific to particulate matter (PM) testing for certain source emissions and control equipment subject to MACT subpart TTTTTT for Secondary Nonferrous Metals Processing, at two of Gulf Reduction Corporation (GRC) facilities (i.e., Dust Manufacturing Division and Metal Division facilities) located in Houston, Texas, based on the premise of ''identical'' source emissions and control equipment located at the same facility?

A1: Yes. EPA conditionally approves a performance test waiver at each GRC facility for PM testing at specifics source emissions and control equipment on the premise that these are considered ''identical'' sources of emissions and control equipment at the facilities to demonstrate initial compliance with NESHAP subpart TTTTTT. However, PM test data for certain source units and their associated air pollution control equipment will be used in lieu of testing other ''identical'' emission sources for PM in order to demonstrate compliance with the standard. EPA conditional approval is based on the review and consideration of a timely submittal of a facility-specific test proposal for multiple identical sources (i.e., identical in terms of manufacturer, design and construction, operational parameters, and maintenance protocols), and provides a testing proposal that is technically sufficient and representative of worst-case emissions in demonstrating compliance at each facility, as detailed in the EPA response letter.

Abstract for [1200029]

Q1: Are a thermal oxidizer (TO) unit and a vapor combustor (VC) used as control devices for the off-gas vent stream from a hydrogen cyanide/acrylonitrile (HCN/ACRN) absorber column at the Lucite International, Inc. (Lucite) facility located in Beaumont, Texas, considered alternate control devices subject to 40 CFR 60.663(f) of NSPS subpart NNN?

A1: No. EPA has determined that the particular process units identified in the Lucite request are not considered ''alternate control devices'' under 40 CFR 60.663(f) of subpart NNN. Instead, we have determined that the TO is a ''boiler'' and that the VC is an ''incinerator'' as these terms are defined in 40 CFR 60.661, and are subject to the compliance testing, continuous monitoring, recordkeeping, and reporting requirements applicable to each such designated unit as specified in NSPS part 60 subpart NNN. Subsequently, 40 CFR 63.l10(d) of NESHAP subpart G should be consulted for ensuring proper implementation of any NSPS and NESHAP overlapping requirements.

Abstract for [1200034]

Q1: Is a thermal desorption system with thermal oxidizer for the treatment of diesel contaminated drill cuttings from deep natural wells, which is being constructed by Pollution Management, Inc. (PMI) in Beebe, Arkansas, subject to NSPS subpart CCCC?

A1: No. EPA determines that the PMI thermal desorption equipment is not subject to the NSPS subpart CCCC because it does not meet the definition of ''Commercial and industrial solid waste incineration (CISWI) unit'' in NSPS subpart CCCC published on December 1, 2000, at 65 FR 7533, which states that a CISWI unit ''means any combustion device that combusts commercial and industrial waste . . . does not include air pollution control equipment or the stack''. In addition, the system designed to volatilize rather than combust since combustion will take place in a thermal oxidizer followed by a baghouse for PM emissions control, meets the definition of thermal desorption found in the U.S. EPA Engineering Bulletin on Thermal Desorption Treatment (Superfund, EPA/540/S–94/501, February, 1994), which states that ''thermal desorption is not incineration, since the destruction of organic contaminants is not the desired result.'' EPA notes that if the material, which the facility accepts, changes, you may be subject to additional regulations under the Resource Conservation and Recovery Act. In addition, the facility remains subject to all applicable State and Federal permitting requirements.

Abstract for [1200035]

Q1: Does EPA extend a prior approved alternative monitoring request for continuous parameter monitoring system (CPMS) in lieu of a continuous opacity monitoring system (COMS) required by 40 CFR 60.45(a) at the NO. 4 unit to all four steam electric generating units located at the Coal Fired Electrical Power Plant Public Service Company of New Mexico (PNM) San Juan Generating Station, subject to NSPS subpart D and A?

A1: Yes. EPA conditionally approves the PNM alternative monitoring request that includes use of each re-located COMS in each of the originally proposed positions, but with the addition of other monitored operational parameters, and your requested program for certification of your proposed CPMS for all four units in a scheduled environmental upgrade program. The approval of an AMP applies to Units No. 4, 3, 2, and 1, of which only Units No. 4, 3, and 1 are subject to NSPS part 60, subpart D, and of which Units No.4, 3, 2, and 1 are subject to applicable requirements of PNM's 2007 federally enforceable air permit. The terms and conditions for the CPMS certification test and on key CPMS data collection and analysis provisions, such as monitoring frequency, averaging time, and compliance levels for the monitored operational parameters, are detailed in the Enclosure to the EPA response letter. EPA notes that the New Mexico Environment Department (NMED) may use our AMP approval for each unit in the implementation of its federally enforceable state rules, applicable federally enforceable air permit conditions, and, at its discretion, its state enforceable Consent Decree for each unit, if it chooses to do so.

Abstract for [M120019]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for site-specific monitoring parameters to be used in daily monitoring for a biological treatment system for Potlatch Forest Products (PFP) Corporation Cypress Bend Mill facility located in McGehee, Arkansas, subject to NESHAP subpart S applicable to the pulp and paper industry?

A1: Yes. EPA conditionally approves the PFP AMP request for site-specific monitoring parameters to be used in the daily monitoring of the open biological treatment system at your pulp and paper Cypress Bend Mill facility. To maintain compliance with the Title V permit, PFP must incorporate the site-specific parameters into its Title V permit for the Cypress Bend Mill facility.

Abstract for [1200036]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) request to allow use of continuous parameter monitoring system (CPMS) in lieu of a continuous opacity monitoring system (COMS) required by 40 CFR 60.45(a) at a steam electric generating unit subject to NSPS subpart D when firing lignite coal, owned by the American Electric Power (AEP) located at the Southwestern Electric Power Company's (SWEPCO) H.W. Pirkey Power Station (Pirkey), near Hallsville and Marshall, Texas?

A1: Yes. EPA conditionally approves the AEP AMP request to address an upgrade of the amount of Sulfur Dioxide (S02) removal planned for Unit l's Wet Flue Gas Desulfurization (WFGD) system resulting in increased SO2 and interference with the opacity readings taken by the stack-located COMS. This is based on AEP's description of the arrangement of the boiler's parallel duct-work and the relationship between the stack-located continuous opacity monitoring system (COMS) and the proposed continuous monitoring system (CMS), which has replaced the stack-located COMS. EPA accepts the use of the ''combiner equation'' to convert opacity data recorded at each of the duct-work COMS devices to equivalent stack opacity data, and accepts the use of induction fan current (in amps) to determine duct-work gas flow rates at each of the COMS devices. If AEP intends to pursue approval of a CPMS, AEP is required to meet specific criteria specified in the EPA response letter, including submittal of the proposed monitored operational parameters for the proposed CPMS to the EPA and the state for review, no later than 90 days prior to conducting a PM and Opacity performance test and prior to conducting a CPMS certification. If AEP does not opt to develop CPMS, AEP may alternatively propose to use a particulate matter continuous emission monitoring system (PM–CEMS). The terms and conditions for the CPMS certification test and on key CPMS data collection and analysis provisions, such as monitoring frequency, averaging time, and compliance levels for the monitored operational parameters, are detailed in the Enclosure to the EPA response letter.

Abstract for [1200037]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for a distillation column and associated equipment to implement NSPS subpart RRR testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN for flow monitoring requirements of Distillation Column C–5222 and associated equipment at Texmark Chemicals, Incorporated (Texmark) located in Galena Park, Texas?

A1: Yes. EPA conditionally approves the Texmark AMP request to implement NSPS subpart RRR for testing, monitoring, and recordkeeping provisions in lieu of complying with corresponding provisions of NSPS subpart NNN for Distillation Column C–5222 vent streams routed to unit flares without any by-pass lines. To ensure that the affected vent streams are routed to appropriate control devices, Texmark is required to maintain a schematic diagram required by 40 CFR 60.705(s) in its initial report to the jurisdictional State Agency, and must maintain a copy on site for the life of the equipment to ensure that affected vent streams are routed to a control device without bypass lines. EPA also approves the request to comply with the recordkeeping requirements of 40 CFR 705(c)(4) in lieu of the recordkeeping requirements of NSPS subpart NNN since these recordkeeping requirements correspond directly to those monitoring requirements to be implemented for the distillation vents under NSPS subpart RRR.

Abstract for [1200045]

Q1: Do NSPS subparts UUU and A apply to calciners and/or dryers used in the processing of kaolin and the production of a catalyst at the W.R. Grace Davison's Lake Charles facility, located in Calcasieu Parish, Louisiana?

A1: Yes. EPA determines that NSPS subpart UUU and A apply to kaolin processing and production facilities if commencement of construction, completion of modification, or completion of reconstruction of these facilities occurred after April 23, 1986, and they meet the definition of ''mineral processing plant'' at 40 CFR 60.731: It processes kaolin clay (a listed mineral); it has the ability to load more than fifty percent of the products mixed with listed minerals, either one at a time or in combination; and, it does not produce any listed minerals, but only processes one or more listed minerals.

Abstract for [1200050]

Q1: Does the particulate matter (PM) concentration limit in 40 CFR 60.254(b)(2) of NSPS subpart Y for mechanical vents exhausting emissions apply to certain buildings at the Duke Energy Cliffside Steam Station in North Carolina? Specifically, does the PM concentration limit apply to mechanical vents which are used for general ventilation on buildings which contain affected facilities.

A1: EPA determines that the PM concentration limit in 40 CFR 60.254(b)(2) does not apply to emissions from mechanical vents which are used for general ventilation from a building containing affected facilities.

Q2: Is a waiver request of the PM concentration performance testing requirement for a mechanical vent that collects emissions from the coal crushers at the Duke Energy Cliffside Steam Station acceptable if no visible emissions are detected over a one-hour period when EPA Method 9 readings are made at the stack exit?

A2: No. EPA determines that the Duke Energy request for a waiver of the requirement to conduct an initial performance test under provisions in 40 CFR 60.8(b)(4) is not justify since it would need to demonstrate compliance through other means that are acceptable. The difficulty associated with testing is not a factor that EPA considers in evaluating the request. 40 CFR 60.8(e) requires the owner or operator of an affected facility to provide performance testing facilities which include test ports, sampling platforms, safe access to the platform(s), and utilities needed for testing.

Abstract for [1200051]

Q: Is Henkel Corporation proposed request to derate the capacity of two boilers at its Enoree, South Carolina facility in order that they will no longer be subject to 40 CFR part 60, subpart Dc, acceptable? The proposal includes the replacement of the existing burner of each boiler with a new lower-rated burner to reduce the heat input capacity to 8.4 million Btu/hour.

A: EPA determines that Henkel Corporation proposed derate method

complies with EPA's criteria on derates. An acceptable derate must consist of a permanent physical change which prevents the boiler from operating at a capacity greater than the derated value. The physical change cannot be easily undone, and a system shutdown must be required to make the change or to reverse it. Since the capacity of the boiler must be reduced to constitute an appropriate derate, changes which are made only to fuel feed systems are not acceptable. If the facility wants to increase the capacity of the boilers after they have been derated, a notification of the proposed modifications must be submitted to the EPA.

Abstract for [1200054]

Q1: Does EPA allow Waste Management of Illinois, Inc. (WMIL), as the permitted operator of the now-closed Settler's Hill Recycling and Disposal Facility and Midway Landfill in Batavia, Illinois, subject to 40 CFR part 60, subpart WWW, to conduct, to implement an alternate remedy consisting of installing a liquid and gas extraction trench and enhancing the landfill cap, and an alternative compliance schedule to address surface scan emissions exceedances that occurred during the 2011 annual surface emissions monitoring event that could not be corrected within the regulatory?

A1: EPA does not need to approve the new trench remedy and corresponding compliance timeline for locations designated as EX–3, 4, 7, 8, 9, as it follows the requirements of corrective action in NSPS subpart WWW at 40 CFR 60.755(c)(4) and will be performed within the 120 calendar day time frame requirement at 40 CFR 60.755(c)(4)(v). EPA approves the request for alternative remedy to the exceedances for locations designated as EX–2 and EX–6 via cap enhancement at the Midway Landfill facility such that the remedy eliminates methane exceedances at both EX–2 and EX–6. WMIL stated that the cap enhancement has been completed as of March 27, 2012, which is within 120 calendar days of the initial exceedance. EPA additionally approves the corresponding timeline for the requested alternative remedy because it matches the timeline required in 40 CFR 60.755(c)(4)(v).

Abstract for [1200055]

Q1: Does EPA allow Waste Management of Illinois, Inc. (WMIL), as the permitted operator of the now-closed Settler's Hill Recycling and Disposal Facility and Midway Landfill in Batavia, Illinois, subject to 40 CFR part 60, subpart WWW, to conduct the alternate remedies of installing a liquid and gas extraction trench and the enhancement of the landfill cap and corresponding compliance schedules for surface scan emissions exceedances that occurred during the March 2012 quarterly surface emissions monitoring event that could not be corrected within the regulatory?

A1: Yes. EPA conditionally approves WMIL's request for an alternative remedy, which includes the separation of the gas control and two collection systems serving the two landfills, upgrade of the blower and motor serving the Midway utility flare, and subsequent re-tuning of the wellfield to address the exceedances at locations EX–4, 5 and 10 of the Midway Landfill. EPA approves these alternative methods as they are consistent with alternative remedies suggested at 40 CFR 60.755(c)(4)(v) and the alternative timeline as it matches the 120 calendar day time frame provided by 40 CFR 60.755(c)(4)(v). WMIL must continue the quarterly monitoring of surface emissions until it can demonstrate no emission exceedances for three consecutive quarterly monitoring periods, as required in 40 CFR 60.756(f) of NSPS subpart WW.

Abstract for [1200060]

Q1: Does EPA approve Citgo Petroleum Corporation (Citgo) Alternative Monitoring Plan (AMP) under 40 CFR 60.13(i)(3) for monitoring a wet gas scrubber (WGS) on a refinery Fluid Catalytic Cracking Unit (FCCU), in lieu of a Continuous Opacity Monitoring System (COMS), to demonstrate compliance with the opacity limit under 40 CFR 60.102(a)(2) Citgo's Lake Charles Manufacturing Complex (LCMC) in Louisiana?

A1: Yes. EPA conditionally approves the Citgo AMP request since moisture in the FCCU exhaust from the WGS interfered with the ability of the COMS to take accurate readings, due to excessive water at the point of measurement. EPA granted final conditional approval of the AMP based on the three scrubber operating limits (OPLs). EPA also clarified that compliance demonstration for each OPL was to be based on a three hour, hourly rolling average basis.

Abstract for [1200061]

Q1: Does EPA approve the Conoco Phillips request to use an alternate performance specification (PS) and alternate span value for conducting relative accuracy checks (RATA) on the Ponca City Refinery East Plant Flare hydrogen sulfide (H2S) continuous emission monitoring system (CEMS) of the CEMS?

A1: No. EPA does not approve the request to use PS–9 in lieu of PS–7 as part of an Alternative RATA Protocol, since it is unacceptable to switch from a more stringent to less stringent PS for demonstrating acceptable performance of the H2S CEMS. Since Conoco Phillips did not provide the requested data, including historical measured flare vent stream H2S concentration data, and data on moisture content, types and expected concentrations of sulfur compounds besides H2S, and the expected sulfur dioxide concentration in the vent stream, and since the use of PS–7 and Method 15 provides sampling and calibration check alternatives to allow viable sampling and testing, EPA withdraws the previous approval issued to Conoco Philips on August 19, 2011, and disapproved the proposed Alternative RATA Protocol for future monitoring efforts.

Abstract for [1200063]

Q1: Source Environmental Services, Inc. (SES) requests a clarification from EPA on whether NSPS subpart Kb requires that all floating roof tanks to be degassed every time they are emptied?

A1: No. EPA determines that the term ''completed empty'' in NSPS subpart Kb does not mean that the tank must be degassed and dried each time it is completely emptied. The standard allows for the roof to rest on legs for a short period of time while the tank is being emptied and subsequently refilled. The EPA response letter references a determination to a similar question dated October 22, 1993, which is available on the ADI Web site. (See ADI number 9400015).

Q2: SES request a clarification from EPA on whether NSPS subpart Kb require all floating roof tanks to be inspected every time they are emptied?

A2: No. EPA determines that the final NSPS subpart Kb regulation does not require an inspection when a tank is emptied and then refilled, although such requirement was initially included in the proposed regulation.

Abstract for [M120022]

Q1: Does EPA approve a site-specific fuel analysis plan for a chemical process fuel gas stream for combustion in utility Boiler No. 15, burning natural gas and a chemical process gas routed from several on-site processes, subject to National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and institutional Boilers and Process Heaters (40 CFR part 63, subpart DDDDD) located at the Eastman Chemical Company (Eastman), located in Longview, Texas?

A1: Yes. EPA evaluated your site-specific fuel analysis plan and approves the plan pursuant to 40 CFR 63.7521(f) in NESHAP subpart DDDDD.

Abstract for [1200065]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) for combusting an off-gas vent stream from a heat transfer hot oil drum (D–703) as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at ExxonMobil Baytown Complex, Texas Refinery?

A1: Yes. EPA evaluated ExxonMobil's AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer valid, because the vent streams now appear to meet one of the exemption criteria of 60.105(a)(4)(iv). Instead, EPA reviewed the information submitted as an application for exemption under 60.105(b)(1). Since the vent stream was demonstrated to be inherently low in sulfur according to 60.105(a)(4)(iv)(D), the fuel gas combustion devices did not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4). The exemption was conditionally approved based on the process operating parameters and monitoring data submitted by the company. The effective date of the exemption is the effective date of the rule change, June 24, 2008. The exemption determination should also be referenced and attached to the facility's new source review and Title V permit for federal enforceability.

Abstract for [1200066]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) for combusting an off-gas vent stream from bonnet and spool vents associated with large motor operated valves (MOVs) as an inherently low-content sulfur stream under NSPS for Refineries part 60 subpart J, at ExxonMobil Baytown Complex, Texas Refinery?

A1: Yes. EPA evaluated ExxonMobil's AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer valid, because the vent streams now appeared to meet one of the exemption criteria of 60.105(a)(4)(iv). Instead, EPA reviewed the information submitted as an application for exemption under 60.105(b)(1). Since the vent stream was demonstrated to be inherently low in sulfur according to 60.105(a)(4)(iv)(C), the fuel gas combustion device did not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4). The exemption was conditionally approved based on the process operating parameters and monitoring data submitted by the company. The effective date of the exemption is the effective date of the rule change, June 24, 2008. The exemption determination should also be referenced and attached to the facility's new source review and Title V permit for federal enforceability.

Abstract for [1200067]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) be approved for combusting an off-gas vent stream from a caustic oxidation unit (COU) knock out drum (D–42) as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at ExxonMobil Baytown Complex, Texas Refinery?

A1: Yes. EPA evaluated the ExxonMobil AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer valid, because the vent streams now appeared to meet one of the exemption criteria of 60.105(a)(4)(iv). Instead, EPA reviewed the information submitted as an application for exemption under 40 CFR 60.105(b)(1). Since the vent stream was demonstrated to be inherently low in sulfur according to 40 CFR 60.105(a)(4)(iv)(D), the fuel gas combustion device did not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4). The exemption was conditionally approved based on the process operating parameters and monitoring data submitted by the company. The effective date of the exemption is the effective date of the rule change, June 24, 2008. The exemption determination should also be referenced and attached to the facility's new source review and Title V permit for federal enforceability.

Abstract for [1200068]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) be approved for combusting an off-gas vent stream from a loading rack vapor recovery unit knock out drum (V–201) at a thermal oxidizer (TC–301) as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at ExxonMobil Baytown Complex, Texas Refinery?

A1: Yes. EPA evaluated the ExxonMobil AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer valid, because the vent streams now appeared to meet one of the exemption criteria of 40 CFR 60.105(a)(4)(iv). Instead, EPA reviewed the information submitted as an application for exemption under 40 CFR 60.105(b)(1). Since the vent stream was demonstrated to be inherently low in sulfur according to 40 CFR 60.105(a)(4)(iv)(D), the fuel gas combustion device did not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 40 CFR 60.105(a)(4). The exemption was conditionally approved based on the process operating parameters and monitoring data submitted by the company. The effective date of the exemption is the effective date of the rule change, June 24, 2008. The exemption determination should also be referenced and attached to the facility's new source review and Title V permit for federal enforceability.

Abstract for [1200069]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) be approved for combusting an off-gas vent stream from a benzene recovery unit in a crude unit heater as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries part 60 subpart J at ExxonMobil Beaumont Complex, Texas Refinery?

A1: Yes. EPA evaluated the ExxonMobil AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer valid, because the vent streams now appeared to meet one of the exemption criteria of 40 CFR 60.105(a)(4)(iv). Instead, EPA reviewed the information submitted as an application for exemption under 40 CFR 60.105(b)(1). Since the vent stream was demonstrated to be inherently low in sulfur according to 40 CFR 60.105(a)(4)(iv)(D), the fuel gas combustion device did not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4). The exemption was conditionally approved based on the process operating parameters and monitoring data submitted by the company. The effective date of the exemption is the effective date of the rule change, June 24, 2008. The exemption determination should also be referenced and attached to the facility's new source review and Title V permit for federal enforceability.

Abstract for [1200070]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for combusting

vapors inherently low-content sulfur stream from marine loading operations of marine vessels, under New Source Performance Standards (NSPS) for Refineries part 60 subpart J at ExxonMobil Beaumont Complex, Texas Refinery?

A1: EPA evaluated the ExxonMobil request in light of the June 24, 2008, changes to NSPS Subpart J (73 FR 35866), and determined that the AMP request is no longer necessary. The definition of fuel gas had been modified to specifically exclude vapors collected and combusted to comply with marine tank vessel loading provisions of MACT subpart Y at 40 CFR 63.562 or 63.651. Therefore, the fuel gas combustion devices do not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4).

Abstract for [M120023]

Q1: Does the NESHAP for Gasoline, subpart BBBBBB, applies to the Intergulf Strang Road Terminal (Intergulf) located in La Porte, Texas?

A1: No. EPA determined that NESHAP subpart BBBBBB does not apply to Intergulf since the individual gasoline blendstocks and other petroleum products handled at the Intergulf Strang Road Terminal meet the definition of transmix. Transmix is defined as a mixture of gasoline and other petroleum distillates that typically contain between 35 and 65 percent gasoline, and with higher concentrations, may have a Reid vapor pressure above the 27.6 kilopascals threshold in the definition of ''gasoline'', as specified in 40 CFR 63.11100. Since transmix is not used as fuel for internal combustion engines, it does not meet the definition of gasoline as defined in 40 CFR 63.11100 and therefore does not trigger applicability of NESHAP BBBBBB.

Abstract for [1200071]

Q1: Does EPA approve an exemption be approved for combusting fuel gas streams from the Udex Process Unit as inherently low-content sulfur streams under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at Marathon Petroleum Company LLC, (Marathon), located in Texas City, Texas?

A1: Yes. EPA evaluated the Marathon AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the fuel gas streams appeared to meet exemption criteria of 40 CFR 60.105(a)(4)(iv)(D). As such, the fuel gas combustion device and the Main Plant Flare, do not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4) for these streams. The effective date of the exemption is October 28, 2010, the date the application for exemption was submitted. If the refinery conditions change and it is determined that any of the streams are no longer exempt, continuous monitoring shall begin within 15 days of the change in accordance with 40 CFR 60.105(a)(4)(iv). The exemption determination should also be referenced and attached to the facility's new source review and Title V permit for federal enforceability.

Abstract for [M120024]

Q1: The Texas Commission on Environmental Quality (TCEQ) request an EPA interpretation of the recordkeeping requirements at 40 CFR 63.654 of NESHAP subpart G and 40 CFR 60.115b of NSPS subpart Kb, as it applies to a regulated entity with several external floating roof storage tanks subject to these requirements. One of the requirements the regulated entity must fulfill is the maintenance of records of raw data obtained in the inspection of storage tank. Should the regulated entity keep the original field notes on site, or may it discard them after transferring the data to the electronic form?

A1: EPA determines that any original field notes should be kept on site. The transferring of raw data from field notes into an electronic database can introduce additional error when data transcription and entry occur, and therefore destroying the field data sheets is not an acceptable practice. This determination is consistent with previously EPA published guidance that addresses air pollution measurement systems and the quality assurance procedures associated with such systems. The Quality Assurance Handbook for Air Pollution Measurement Systems indicates that the original field data sheets must be preserved whenever any sort of emissions sampling or equipment testing, such as measuring seal gaps in a storage tank, is performed.

Abstract for [1200072]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for monitoring hydrogen sulfide (H2S) in lieu of installing a continuous emission monitoring system (CEMS) at a refinery loading dock flare covered under NSPS subpart J at the TOTAL Petrochemicals USA Inc., Port Arthur Refinery (TOTAL Refiner), Texas?

A1: No. EPA does not approve TOTAL Petrochemicals AMP request. This determination is made after several attempts over the past few years to allow the company adequate time to submit sufficient process information about its operation and characteristics of the loading dock vent gas streams, and after subsequently determining that the company could not ascertain whether or not the AMP request was still necessary.

Abstract for [1200073]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) for combusting vent streams from a truck and railcar loading rack as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, for the Valero Three Rivers Refinery (Valero) facility in Live Oak County, Texas?

A1: Yes. EPA evaluated the Valero AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer necessary, because the pilot and assist gas vent streams appeared to meet exemption criteria of 40 CFR 60.105(a)(4)(iv)(A), the refined benzene, gasoline and diesel vapors appeared to meet the criteria of 40 CFR 60.105(a)(4)(iv)(B), and the light cycle oil (LCO) vapors appeared to meet the criteria of 40 CFR 60.105(a)(4)(iv)(D). As such, the fuel gas combustion device does not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4) for these streams. The effective date of the exemption is June 24, 2008. If refinery operations change such that Valero determines that the stream is no longer exempt, continuous monitoring shall begin within 15 days of the change in accordance with 40 CFR 60.105(a)(4)(iv). For the LCO stream exempted under 40 CFR 60.105(a)(4)(iv)(D), instead refer to the procedures in 40 CFR 60.105(b)(3)(i–iii) if changes in operating conditions or stream composition occur.

Abstract for [1200076]

Q1: Does EPA approve exemptions in lieu of two approved Alternative Monitoring Plans (AMPs) for vent streams from Steam Methane Reformer Pressure Swing Adsorption Off-Gas and Catalytic Reformer Unit Fuel Gas Drums, as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries, part 60, subpart J, at Valero Refining Corpus Christi West Plant (Valero CC West) in Nueces County, Texas?

A1: Yes. EPA evaluated Valero CC West request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the

AMPs are no longer necessary for the specified fuel gas streams since the vent streams are considered inherently low in sulfur since they are produced in process units intolerant to sulfur contamination and meet the exemption requirement of 40 CFR 60.l05(a)(4)(iv)(C). Therefore, the fuel gas combustion devices do not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4).

Abstract for [1200077]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) for combusting a Sulfur Collection Header (39FA1006) fuel gas stream from the C-Train Sulfur Recovery Unit (SRU) under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at Valero Refining Texas, Houston Plant (Valero Houston), Houston, Texas?

A1: Yes. EPA evaluated the Valero Houston AMP request in light of changes included in the final amendment to NSPS subpart J on June 24, 2008 (73 FR 35840) and determined that an AMP is not needed since the rule requirements for the Sulfur Collection Header (39FA1006) fuel gas stream from the C-Train SRU are being met. The C-Train SRU is a Claus sulfur recovery plant with oxidation control systems followed by incineration, therefore the fuel gas stream is subject to the continuous monitoring required by 40 CFR 60.105(a)(5).

Abstract for [1200078]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) for combusting Sulfur Storage Tank (39FB1001) and Sulfur Loading Arm fuel gas streams from the C-Train Sulfur Recovery Unit (SRU) under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at Valero Refining Texas, Houston Plant (Valero Houston), Houston, Texas?

A1: Yes. EPA evaluated the Valero Houston AMP request in light of changes included in the final amendment to NSPS subpart J on June 24, 2008 (73 FR 35840) and determined that an AMP is not necessary for the specified fuel gas streams since the NSPS subpart J requirements for the Sulfur Storage Tank (39FB1001) and Sulfur Loading Arm fuel gas streams from the C-Train SRU are being met. The C-Train SRU is a Claus sulfur recovery plant with oxidation control systems followed by incineration, therefore the fuel gas streams are subject to the continuous monitoring required by 40 CFR 60.105(a)(5).

Abstract for [1200079]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) be approved for combusting Sulfur Pit (46AD6202) and Sulfur Loading Arm (46LO6201) fuel gas streams from the B-Train Sulfur Recovery Unit (SRU) under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at Valero Refining Texas, Houston Plant (Valero Houston), Houston, Texas?

A1: Yes. EPA evaluated the Valero Houston AMP request in light of changes included in the final amendment to NSPS subpart J on June 24, 2008 (73 FR 35840) and determined that an AMP is not necessary since the NSPS subpart J requirements for the Sulfur Pit (46AD6202) and Sulfur Loading Arm (46LO6201) fuel gas streams from the B-Train are being met. The B-Train SRU is a Claus sulfur recovery plant with oxidation control systems followed by incineration, therefore the fuel gas streams are subject to the continuous monitoring required by 40 CFR 60.105(a)(5) and not subject to the monitoring requirements of 40 CFR 60.105(a)(3) or 60.101(a)(4).

Abstract for [1200081]

Q1: Does EPA approve an exemption in lieu of an Alternative Monitoring Plan (AMP) for combusting a vent stream from a hydrogen plant pressure swing absorber (PSA) as an inherently low-content sulfur stream under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at Western Refining Company, L.P. (Western Refining) Hydrogen Plant located in El Paso, Texas?

A1: Yes. EPA evaluated the Western Refining AMP request in light of changes made to NSPS subpart J on June 24, 2008 (73 FR 35866), and determined that the AMP request was no longer necessary, because the refinery's Hydrogen Plant PSA vent gas stream is inherently low in sulfur and therefore appeared to meet the exemption criteria of 40 CFR 60.105(a)(4)(iv)(C), and it is combusted in the steam reformer heater and Rheniformer flare. As such, the fuel gas combustion devices do not need to meet the monitoring requirements of either 40 CFR 60.105(a)(3) or 60.105(a)(4) for this stream. The effective date of the exemption is June 24, 2008. If refinery operations change such that Western Refinery determines that the stream is no longer exempt, continuous monitoring must begin within 15 days of the change in accordance with 40 CFR 60.105(a)(4)(iv).

Abstract for [1200084]

Q1: Does EPA approve a request for an alternative monitoring procedure (AMP) for two new proposed kilns (known collectively as EU 056) located at the 3M Cottage Grove facility in Minnesota (3M), since it is expected that the wet scrubbing system for EU 056 will achieve a particulate matter (PM) emission rate an order of magnitude below the emission rate required under NSPS subpart UUU Standards of Performance for Calciners and Dryers in Mineral Industries, and based on performance testing conducted on a similar system?

A1: Yes. EPA approves the 3M AMP request since EPA believes that monitoring and recording the scrubbing liquid pressure is a reasonable alternative to monitoring and recording the pressure loss of the gas through the scrubber required in 40 CFR 60.734(d) of subpart UUU, and that it is similar to and based on previous EPA AMP approvals. EPA agrees with the 3M recommendation that a deviation is any instance where the scrubbing liquid supply pressure is more than 20 percent below the average value determined, in accordance with 40 CFR 60.736(c), during a recently-conducted performance test of EU 056 that demonstrates compliance with the PM standard.

Abstract for [1200085]

Q1: Is EU 028, a mixer/dryer that processes a very wet (greater than 50 percent moisture) alumina slurry located significantly upstream of kilns, subject to NSPS subpart UUU, at the 3M facility in Cottage Grove, Minnesota?

A1: No. EPA has determined that the mixer/dryer EU 028 is not subject to NSPS subpart UUU requirements because it does not meet the definition of mineral processing plant under the rule since it processes alumina slurry that contains less than 50 percent alumina.

Abstract for [M120025]

Q1: Does EPA approve an alternative monitoring plan (AMP) for use of quarterly comparative temperature monitoring in lieu of the quarterly calibration verification requirements for thermocouples, which are located below the catalyst bed in each of two oxidizers required under the Paper and Other Web Coating NESHAP, at the 3M facility in Cottage Grove, Minnesota?

A1: Yes. EPA approves of the use of quarterly comparison of thermocouple temperature readings in lieu of the calibration verification requirements in 40 CFR 63.3350(e)(9). EPA believes

monitoring and recording the scrubbing liquid pressure is a reasonable alternative to monitoring and recording the pressure loss of the gas through the scrubber. EPA also concurs with the 3M recommendation that a deviation is any instance where the scrubbing liquid supply pressure is more than 20 percent below the average value determined, in accordance with 40 CFR 60.736(c), during a recently-conducted performance test of EU 056 that demonstrates compliance with the PM standard.

Abstract for [M120028]

Q1: Does EPA approve an alternative monitoring plan (AMP) for use of an acoustic monitor capable of detecting the presence of a flare pilot flame in lieu of a thermocouple for demonstrating compliance with the NSPS subpart A, and NESHAP Subparts A and CC at Utility Flare 84ME–27 at the Flint Hills Resources—Pine Bend Refinery (Flint Refinery)?

A1: Yes. EPA approves the Flint Refinery AMP request based on the information provided, including a noise survey at the site. EPA has determined that the acoustic monitor is appropriate for detecting the presence of a flare pilot flame given the ambient background noise magnitude and profile created by nearby operating equipment.

Abstract for [M120030]

Q1: Is a metal etching process using chromic acid and an electrical current, though in the reverse of the typical plating process (i.e., with the metal part serving as the anode), to be installed at the Teikuro Corporation Springfield facility in Ohio (Teikuro), subject to the NESHAP for Area Source Standards for Plating and Polishing Operations, subpart WWWWWW?

A1: Yes. EPA determines that Teikuro planned etching process meets the definition of electropolishing in 40 CFR 63.11504(a)(vi) because the process you described involves an electrolytic process with the metal part serving as the anode and a bath containing chromium. Therefore, the planned etching process is required to meet the NESHAP subpart WWWWWW rule requirements.

Abstract for [1200089]

Q1: Does EPA approve an Alternative Monitoring Plan (AMP) for combusting a Sulfur Collection Header (39FA1006) fuel gas stream from the C-Train Sulfur Recovery Unit (SRU) under New Source Performance Standards (NSPS) for Refineries part 60 subpart J, at Valero Refining Texas, Houston Plant (Valero Houston), Houston, Texas?

A1: Yes. EPA evaluated the Valero Houston AMP request in light of changes included in the final amendment to NSPS subpart J on June 24, 2008 (73 FR 35840) and determined that an AMP is not necessary since the NSPS subpart J requirements for combusting a Sulfur Collection Header (39FA1006) fuel gas stream from the C-Train SRU are being met. The stream is combusted in the SRU Tail Gas Incinerator 39CB2001, which is equipped with continuous monitoring required by 40 CFR 60.105(a)(5). The C-Train SRU is a Claus sulfur recovery plant with oxidation control systems followed by incineration, therefore, the fuel gas stream is subject to the continuous monitoring required by 40 CFR 60.105(a)(5) and not subject to the monitoring requirements of 40 CFR 60.105(a)(3) or 60.101(a)(4).

Abstract for [M120031]

Q1: Does EPA approve Montana-Dakota Utilities Company request for confirmation of status of R. M. Heskett Station Units 1 and 2 in ''unit designed for low rank virgin coal'' subcategory under the Mercury and Air Toxics (MATS) NESHAP rule, subpart UUUUU?

A1: Yes. Based on review with the Office of Air Quality Planning and Standards and the MATS rule applicable to coal and oil-fired electric utility steam generating units, EPA confirmed the referenced units are in the subcategory.

Abstract for [M120032]

Q: Can, and under what conditions may, a secondary aluminum production reverberatory furnace change its classification from Group 1 to Group 2 under the Secondary Aluminum NESHAP subpart RRR rule, at the Kalamazoo facility located in Michigan?

A: Yes. EPA concludes that the Kalamazoo facility may change the furnace classification upon approval by the regulatory authority and upon meeting the conditions established in the EPA response letter, consistent with NESHAP subpart RRR requirements. The furnace must be operated within one (and only one) of the three proposed operating modes for the entirety of a given melt cycle, which are: Group 1 furnace with add-on air pollution control devices; Group 1 furnace without add-on air pollution control devices; and Group 2 furnace.

Abstract for [1200091]

Q: Intertek Testing Services (Intertek) request guidance on whether EPA allows certification testing for wood heating appliances subject to the New Source Performance Standard for New Residential Wood Heating Appliances, NSPS subpart AAA, to be conducted at manufacturing facilities?

A: EPA clarifies to Intertek that certification testing for compliance with the NSPS subpart AAA may be conducted at a manufacturing facility, provided staff from EPA accredited laboratories conduct the testing and follow the offsite testing guidelines testing guidelines included as an attachment to the EPA response letter. Only equipment purchased, calibrated and used by the EPA accredited laboratory may be used to conduct the testing.

Abstract for [Z120004]

Q: Does EPA grant Magellan Pipeline Company (Magellan) a one-year compliance extension from the Reciprocating Internal Combustion Engines (RICE) NESHAP regulations at 40 CFR part 63 subpart ZZZZ to install emission controls at 26 diesel RICE located in Oklahoma, Missouri, Kansas, Nebraska, Iowa, Minnesota, South Dakota, and North Dakota?

A: Yes. Per 40 CFR part 63(i)(4) and (6), EPA extends the compliance date from May 3, 2013 to May 3, 2014 to allow Magellan Pipeline additional time to install emission controls at 26 diesel RICE and thereby comply with the RICE NESHAP regulations at 40 CFR part 63, subpart ZZZZ. The extension is granted under the conditions, which support compliance with the RICE NESHAP regulations and are outlined in the EPA response letter.

Abstract for [1200092]

Q: Does EPA grant a National Security Exemption (NSE) for 240 Cummins Model 6T8.3–G2 diesel engines to be used at an Intercontinental Ballistic Missile (ICBM) facility at W. E Air Force Base?

A: Yes. EPA grants the NSE for the 240 Cummins Model 6T8.3–G2 diesel engines. These engines will provide backup and emergency power to the ICBM Minuteman III Launch Facilities (LFs) and Missile Alert Facilities (MAFs) in the event of commercial power loss. The NSE is granted because the electronic fuel controls used by these engines to comply with the Compression Ignition Reciprocating Internal Combustion Engine (RICE) regulations at 40 CFR part 60, subpart IIII are susceptible to electromagnetic pulse and shock which may occur during nuclear attack under wartime conditions and, therefore, cannot be used in this application.

Abstract for [WDS–145]

Q: Does EPA approve the alternative testing request to allow sources subject to the New Source Performance Standard for New Residential Wood Heaters at 40 CFR part 60, subpart AAA, to use the Canadian test protocol CSA B415, to determine thermal energy efficiency ratings for wood stoves and pellet stoves per the guidelines at 40 CFR part 60.636(i)(3) in lieu of the default efficiency ratings (63 percent for noncatalytic wood heaters, 72 percent for catalytic wood heaters, and 78 percent for pellet stoves)?

A: Yes. EPA approves the alternative testing for manufacturers of wood heaters and pellets to use CSA B415 to determine thermal efficiency ratings for compliance with 40 CFR part 60, subpart AAA. The CSA B415 testing must be conducted by an EPA accredited laboratory and use the higher heating value of the fuel.

Dated: April 17, 2013.

Lisa Lund,

Director, Office of Compliance.

[FR Doc. 2013–11204 Filed 5–9–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9812–5; Docket ID No. EPA–HQ–ORD–2013–0357]

Notice of Workshop and Call for Information on Integrated Science Assessment for Oxides of Sulfur

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Workshop; Call for Information.

SUMMARY: The U.S. EPA Office of Research and Development's National Center for Environmental Assessment (NCEA) is preparing an Integrated Science Assessment (ISA) as part of the review of the primary National Ambient Air Quality Standards (NAAQS) for oxides of sulfur (SO_X) (for which the indicator is sulfur dioxide [SO_2]). This ISA will update the scientific assessment presented in the Integrated Science Assessment for Sulfur Oxides—Health Criteria (EPA 600/R–08/047F), published in September 2008. Interested parties are invited to assist the EPA in developing and refining the scientific information base for the review of the NAAQS for SO_X by submitting recent research studies that have been published, accepted for publication, or presented at a public scientific meeting.

The EPA is also announcing that a workshop entitled ''Kickoff Workshop to Inform EPA's Review of the Primary SO_2 NAAQS'' is being organized by NCEA and the EPA Office of Air and Radiation's Office of Air Quality Planning and Standards (OAQPS). The workshop will be held June 12–13, 2013, in Research Triangle Park, North Carolina. The workshop will be open to attendance by interested public observers on a first-come, first-served basis up to the limits of available space.

Additionally, in the near future, the EPA Scientific Advisory Board (SAB) will be forming a Clean Air Scientific Advisory Committee (CASAC) panel for the SO_2 NAAQS health review.

DATES: The workshop will be held on June 12–13, 2013. All communications and information submitted in response to the call for information should be received by EPA by June 10, 2013.

ADDRESSES: The workshop will be held at U.S. EPA, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina. An EPA contractor, ICF International, is providing logistical support for the workshop. Please register by going to *https://sites.google.com/site/soxkickoffworkshop/*. The pre-registration deadline is May 31, 2013. Please direct questions regarding workshop registration or logistics to Whitney Kihlstrom at *EPA_NAAQS_Workshop@icfi.com* or by phone at 919–293–1646. For specific questions regarding technical aspects of the workshop see the section of this notice entitled **FOR FURTHER INFORMATION CONTACT**.

Information in response to the call for information may be submitted electronically, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the section of this notice entitled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For details on the period for submission of research information from the public, contact the Office of Environmental Information (OEI) Docket; telephone: 202–566–1752; facsimile: 202–566–9744; or email: *Docket_ORD@epa.gov.* For technical information, contact Tom Long, Ph.D., NCEA; telephone: 919–541–1880; facsimile: 919–541–2985; or email: *long.tom@epa.gov* or Amy Lamson, Ph.D., OAQPS; telephone: 919–541–4383 or email: *lamson.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About the Project

Section 108(a) of the Clean Air Act directs the Administrator to issue ''air quality criteria'' for certain air pollutants. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare, which may be expected from the presence of such pollutant in the ambient air. . . .'' Under section 109 of the Act, EPA is then to establish National Ambient Air Quality Standards (NAAQS) for each pollutant for which EPA has issued criteria. Section 109(d) of the Act requires EPA to review periodically, and, if appropriate, to revise existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. EPA is also to determine whether it is appropriate to revise the NAAQS based on the revised air quality criteria.

Oxides of Sulfur (SO_X) are one of six ''criteria'' pollutants for which EPA has established NAAQS. Periodically, EPA reviews the scientific basis for these standards by preparing an Integrated Science Assessment (ISA). The ISA, along with additional technical and policy assessments conducted by OAQPS, form the scientific and technical bases for EPA decisions on the adequacy of the SO_2 NAAQS and the appropriateness of revising that standard.

At the start of a NAAQS review, EPA issues an announcement of the review and notes the initiation of the development of the ISA. At that time, EPA also issues a request that the public submit scientific literature that they want to bring to the attention of the Agency for consideration in the review process. CASAC, an independent scientific advisory committee whose role is mandated by the Clean Air Act, is charged with independent expert scientific review of EPA's draft ISAs. As the process proceeds, the public will have opportunities to review and comment on draft SO_X ISAs. These opportunities will also be announced in the **Federal Register**.

For the review of the primary SO_2 NAAQS being initiated by this notice, the Agency is interested in obtaining additional new information, particularly concerning toxicological studies of effects of controlled exposure to SO_X on laboratory animals, humans, and in vitro systems as well as epidemiologic (observational) studies of health effects associated with ambient exposures of human populations to SO_X. EPA also seeks recent information in other areas of SO_X research such as chemistry and physics, sources and emissions, analytical methodology, transport and transformation in the environment, and ambient concentrations. This and other selected literature relevant to a review

of the SO_2 NAAQS will be assessed in the forthcoming SO_X ISA.

As part of this review of the SO_2 NAAQS, EPA intends to sponsor a workshop on June 12–13, 2013, in Research Triangle Park, North Carolina to highlight significant new and emerging SO_X research, and to make recommendations to the Agency regarding the design and scope of the review for the primary (health-based) SO_2 standards to ensure that it addresses key policy-relevant issues and considers the new science that is relevant to informing our understanding of these issues. In addition, other opportunities for submission of new peer-reviewed, published (or in-press) papers will be possible as part of public comment on the draft ISAs that will be reviewed by CASAC. Workshop discussions are intended to build upon three prior publications or events (see *http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html* to obtain a copy of these and other related documents):

- Primary National Ambient Air Quality Standard for Sulfur Dioxide; Final Rule (40 CFR Parts 50, 53, and 58, June 22, 2010). The preamble to the final rule included detailed discussions of policy-relevant issues central to the last review.
- Integrated Science Assessment for Sulfur Oxides—Health Criteria (EPA 600/R–08/047F, September 2008).
- Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standard (EPA 452/R–09/007, July 2009).

Based in large part on the input received during this workshop, EPA will develop a draft integrated review plan for the SO_X review that will outline the schedule, process, and approaches for evaluating the relevant scientific information and addressing the key policy-relevant issues to be considered in this review. CASAC will be asked to conduct a consultation with the Agency on the draft integrated review plan, and the public will have the opportunity to comment on it as well. The final integrated review plan will be used to frame each of the major elements of the SO_X review under the NAAQS review process: An integrated science assessment, a risk/exposure assessment, and a policy assessment.

II. How To Submit Technical Comments to the Docket

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2013–0357 by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_ORD@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460. The phone number is 202–566–1752.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number for the Public Reading Room is 202–566–1744. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2013–0357. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means 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 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, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *www.epa.gov/epahome/dockets.htm.*

Docket: Documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: May 2, 2013.

Debra B. Walsh,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2013–11197 Filed 5–9–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities: Proposed Collection Renewal; Comment Request Re Occasional Qualitative Surveys

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity, as required by the Paperwork Reduction Act of 1995 (4 U.S.S. chapter 35), to comment on renewal of its generic information collection entitled, ''Occasional Qualitative Surveys'' (OMB No. 3064–0127).

DATES: Comments must be submitted on or before July 9, 2013.

ADDRESSES: Interested parties are invited to submit written comments. All comments should refer to the name of the collection. Comments may be submitted by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/propose.html.*
- *Email: comments@fdic.gov.*
- *Mail:* Leneta G. Gregorie (202.898.3719), Counsel, Federal Deposit Insurance Corporation, 550 17th Street NW., Room NY–5050, Washington, DC 20429.

• *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

A copy of the comments may also be submitted to the FDIC Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For further information about this information collection, please contact Leneta G. Gregorie, by telephone at (202) 898–3719 or by mail at the address identified above.

SUPPLEMENTARY INFORMATION: The FDIC is requesting OMB approval to renew the following information collection:

Title: Occasional Qualitative Surveys.

OMB Number: 3064–0127.

Estimated number of surveys per year: 15.

Estimated response time per survey: 1 hour.

Estimated number of respondents per survey: 850 hours.

Total Annual Burden: 12,500 hours.

General Description of Collection: The information collected in these surveys is anecdotal in nature, that is, samples are not necessarily random, the results are not necessarily representative of a larger class of potential respondents, and the goal is not to produce a statistically valid and reliable database. Rather, the surveys are expected to yield anecdotal information about the particular experiences and opinions of members of the public, primarily staff at respondent banks or bank customers. The information is used to improve the way FDIC relates to its clients, to develop agendas for regulatory or statutory change, and in some cases to simply learn how particular policies or programs are working, or are perceived in particular cases.

Request for Comment

Comments are invited on: (a) Whether these collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimate of the burden of the information collection, 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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 6th day of May, 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2013–11057 Filed 5–9–13; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission

TIME AND DATE: May 15, 2013; 10:00 a.m.

PLACE: 800 North Capitol Street NW., First Floor Hearing Room, Washington, DC

STATUS: The meeting will be held in Open Session.

MATTERS TO BE CONSIDERED: 1. Staff Briefing on Agency Initial Draft FY 2014–2018 Strategic Plan

2. Licensing, Financial Responsibility Requirements, and General Duties for Ocean Transportation Intermediaries

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–11219 Filed 5–8–13; 4:15 pm]

BILLING CODE 6730–01–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 May 28, 2013.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Jerry K. Anderson,* acting as Plan Administrator of the Commerce Bank and Trust Holding Company Employee Stock Ownership Plan, both of Topeka, Kansas; to retain voting shares of Commerce Bank and Trust Holding Company, and thereby indirectly retain voting shares of CoreFirst Bank & Trust, both in Topeka, Kansas.

Board of Governors of the Federal Reserve System, May 7, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–11148 Filed 5–9–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–18280–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0308, scheduled to expire on June 30, 2013. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before June 10, 2013.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0308 and document identifier HHS–OS–18280–30D.

Information Collection Request Title: The Effect of Reducing Falls on Acute and Long-Term Care Expenses.

OMB No.: 0990–0308.

Abstract: ASPE is conducting a demonstration and evaluation of a

multi-factorial fall prevention program to measure its impact on health outcomes for the elderly as well as acute and long-term care use and cost. The study is being conducted among a sample of individuals with private long-term care insurance who are age 75 and over using a multi-tiered random experimental research design to evaluate the effectiveness of the proposed fall prevention intervention program. The project began in Spring 2008 and is expected to be completed in December 2014.

Need and Proposed Use of the Information: The project will provide information to advance Departmental goals of reducing injury and improving the use of preventive services to positively impact Medicare use and spending.

Likely Respondents: Adults age 75 or older.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Telephone Screen	Active Control Group (ACG)/Experimental Group (EG).	835	1	20 minutes	278
In-person interview	EG	435	1	1.25 hours	544
Jump start phone call	EG	435	1	30 minutes	218
Quarterly phone calls	ACG/EG	835	4	10 minutes	556
Final Telephone Screen	ACG/EG	167	1	20 minutes	56
Final In-person interview	EG	167	1	1.25 hours	209
Total					1861

Keith A. Tucker,

Information Collection Clearance Officer.

[FR Doc. 2013–11177 Filed 5–9–13; 8:45 am]

BILLING CODE 4150–39–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–13EP]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Million Hearts® Hypertension Control Challenge—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC proposes to launch the Million Hearts® Hypertension Control Challenge to identify clinical practices and health systems that have been successful in achieving high rates of hypertension control and to develop models for dissemination. The most successful clinical practices or health plans will be recognized as Million Hearts® Hypertension Control Champions.

CDC requests OMB approval to collect the information needed to identify, qualify, and rank applicants for recognition through the Million Hearts® Hypertension Control Challenge. Interested providers or clinical programs voluntarily self-nominate their practice or healthcare system by completing a web-based nomination form located on the Challenge.gov web portal. The nomination process will include submission of the minimum amount of data needed to provide evidence of clinical success in achieving hypertension control, including: (a) Two point-in-time measures of the clinical hypertension control rate for the patient population, (b) the size of the clinic population served, and (c) a description of the sustainable systems adopted to achieve hypertension control rates.

CDC scientists or contractors will assign a preliminary score to each submitted nomination form. Those with the highest preliminary scores will be further reviewed by a CDC-sponsored panel of three to five experts in hypertension control. The panel will provide CDC with a ranked list of nominees.

Finalists will be asked to participate in a data verification process that includes verification of how information was obtained from electronic records, remote electronic record or chart review, on-site review, or verification with other sources. Finalists may be eliminated based on the results of data verification.

Each remaining finalist, or Champion, will be asked to participate in a semi-structured interview. The interview will provide detailed information about the strategies employed by the practice or health system to achieve exemplary rates of hypertension control, including barriers and facilitators for those strategies.

OMB approval is requested for three years to support three annual Challenges.

There are no costs to respondents other than their time. The total estimated burden hours are 958.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Physicians (Single or Group Practices or Health System).	Million Hearts® Hypertension Control Champion Nomination Form.	1,735	1	.5
Finalists	Million Hearts® Hypertension Control Champion Data Verification Form.	30	1	1
Selected Champion	Interview Guide: Million Hearts® Hypertension Control Champion.	30	1	2

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–11059 Filed 5–9–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0915]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to 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

Formative Research to Support the Development of Sickle Cell Disease Educational Messages and Materials for the Division of Blood Disorders (0920–0915, Expired 01/31/2013)—Reinstatement—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks to improve the quality of life of people living with sickle cell disease (SCD). To accomplish this goal, CDC aims to address the need for educational messages and materials for adolescents, young adults, adults, and older adults living with SCD. CDC is interested in understanding the informational needs of these audiences related to the adoption of healthy behaviors and the prevention of complications associated with sickle cell disease. To develop valuable messages and materials, CDC will conduct formative focus groups with people with SCD across the country. Participants will stem from four urban centers as well as more remote, rural areas. Based on the findings from the formative focus groups, CDC will develop and test draft messages.

A total of 10 focus groups will be conducted. Eight focus groups with people with SCD would be held in four cities: Atlanta, GA; Detroit, MI; Oakland, CA; and Philadelphia, PA. Two in-person focus groups—one with males and one with females—will be conducted in each city with each target audience: adolescents aged 15–17, young adults aged 18–25, adults aged 26–35, and older adults 36 and over. To reach more rural participants, two telephone focus groups will be conducted: one with female adolescents aged 15–17 and a second with male older adults aged 36 and older.

The focus groups will be conducted with eight to nine participants in each and will last 2 hours. As part of the focus group, participants will complete an informed consent or adolescent assent form before discussion begins. The parents of the expected 27 adolescent participants (three groups of 9 each) will fill out a permission form to provide their consent in advance of the groups. The use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. In total, up to 90 people with SCD will participate in the focus group data collection. It is estimated that 120 potential participants will need to be screened to reach the target of 90 participants. The estimated time per response for screening and recruitment is 12 minutes.

CDC requests OMB approval to extend clearance for one year. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 204.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)
Parents of adolescents (aged 15–17) living with SCD. Young adults (aged 18–25) living with SCD. Adults (aged 26–35) living with SCD. Older adults (aged 36+) living with SCD.	Participant Screener and Recruitment Script	120	1	12/60
Adolescents (aged 15–17) living with SCD Young adults (aged 18–25) living with SCD. Adults (aged 26–35) living with SCD. Older adults (aged 36+) living with SCD.	Focus Group Moderator's Guide	90	1	2

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–11188 Filed 5–9–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announce the following meeting of the aforementioned committee:

Times and Dates: 8:00 a.m.–5:00 p.m., June 19, 2013; 8:00 a.m.–4:00 p.m., June 20, 2013.

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent ''Oz'' Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. Further, under provisions of the Affordable Care Act, at section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Matters To Be Discussed: The agenda will include discussions on: General recommendations, influenza, Japanese encephalitis vaccine, pertussis vaccine, Herpes zoster vaccine, rotavirus vaccines, human papillomavirus vaccines, and vaccine supply. Recommendation votes are scheduled for influenza and Japanese encephalitis vaccine. Time will be available for public comment. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Felicia Betancourt, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road NE., MS–A27, Atlanta, Georgia 30333, Telephone: (404) 639–8836, Email: *ACIP@CDC.GOV*

The meeting is webcast live via the World Wide Web; for instructions and more information on ACIP please visit the ACIP Web site: *http://www.cdc.gov/vaccines/acip/index.html.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–11112 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 25743–25746, dated May 2, 2013) is amended to establish the Office of Safety, Security, and Asset Management, Office of the Chief Operating Officer, Office of the Director, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the titles and functional statements for the Buildings and Facilities Office (CAJC); the Logistics Management Branch (CAJHW), Procurement and Grants Office (CAJH); the Office of Security and Emergency Preparedness (CAJJ); Office of Safety, Health and Environment (CAJP); insert the following:

Office of Safety, Security and Asset Management (CAJS). The Office of Safety, Security and Asset Management (OSSAM) serves as the lead organizational entity for providing a safe, secure, functional, and healthy workplace environment for Centers for Disease Control and Prevention (CDC) staff while ensuring environmental stewardship and appropriate management of agency assets.

Office of the Director (CAJS1). (1) Directs, manages, coordinates and evaluates the programs and activities of OSSAM service offices; (2) develops goals and objectives and provides leadership, policy formulation and guidance in program planning and development; and (3) provides advice and counsel to the CDC Director, the Chief Operating Officer, and other senior Office of the Director (OD) and Centers/Institute/Offices (CIO) officials on all OSSAM programs and activities.

Office of Financial, Administrative, and Information Services (CJAS12). (1) Provides administrative guidance, advice, and support to OSSAM employees; (2) manages OSSAM information technology support, including system development, maintenance, design and implementation; (3) provides direction, strategy, analysis, and operational support in all aspects of OSSAM's human resources operations; (4) develops and implements internal policies and procedures, including developing related communications; (5) serves as the performance ombudsman for OS SAM; (6) provides office space allocation for all OSSAM programs; (7) serves as the point of contact between OSSAM OD and the Office of the Chief Financial Officer; (8) provides funding ceiling information to each OSSAM office; (9) manages all OSSAM salary and budget spending; (10) provides oversight, guidance and approval for the procurement process OS SAM-wide; (11) provides oversight of property accountability, including appointing an OSSAM property accountability officer; (12) provides guidance and oversight related to the records management requirements and process; and (13) establishes and enforces OSSAM-related travel policies.

Office of Operations (CAJS13). (1) Implements, maintains, and updates CDC's Integrated Emergency Management Program, Emergency Response Plans (ERPs) and CDC Continuity Of Operations (COOP) communications vehicles; (2) conducts and evaluates annual tabletop, functional, and full-scale exercises for all CDC facilities with ERPs; (3) recommends future emergency management and emergency response-related programs, policies, and/or procedures; (4) oversees technical programs to ensure a safe, secure and healthy workplace while ensuring all worksite issues are properly addressed and brought to closure; (5) oversees the Quarterly Performance Review process; and (6) provides oversight and guidance to OSSAM liaison officers who support programs as the key contact for matters related to safety, security, facilities, logistics and sustainability.

Public Health and Intelligence Office (CAJS14). (1) Provides leadership and operational and technical support for development and implementation of intelligence activities; (2) analyzes and disseminates intelligence related to public health, medical and scientific

intelligence, counterintelligence, insider threat, and global security; (3) researches, compiles, produces, and provides classified and unclassified briefings; (4) performs prepublication review of classified and sensitive information; (5) serves as the CDC liaison with U.S. intelligence community agencies; (6) provides global security oversight in coordination with U.S. government agencies, international organizations, and non-governmental organizations; (7) identifies training needs and recommends specific training objectives to be met and the methods to achieve them (i.e. Security Awareness, Counterintelligence Awareness; Foreign Travel Safety Brief); (8) develops, implements, and presents sound and well-grounded training programs to prepare agency staff members pending deployments or travel abroad; (9) performs security assessments of and technical assistance to agency international facilities; (10) supports agency international operational goals through membership on the Department of State Overseas Security Policy Board; (11) provides oversight of the Defensive Counterintelligence and Insider Threat program; (12) processes non-United States citizen requests for physical or logical access; (13) provides guidance over all security issues related to foreign travel matters; (14) provides policy and implementation guidance on all standards and requirements related to the processing and storing of controlled unclassified information; (15) manages and operates the agency's Sensitive Compartmented Information Facility (SCIF) and its secure communications systems; (16) maintains accreditation of the agency's SCIF; (17) manages and operates collateral-level secure facilities nationally; (18) provides policy and implementation guidance on the standards for using classified document control for CDC; (19) provides policy and implementation guidance on all standards and requirements related to the processing and storing of classified information by the agency; (20) develops and administers a physical protection plan for all national security information and material held or processed by the agency in accordance with established laws, mandates, and government-wide policies; (21) acts as Communications Security Custodian for all classified matters involving the National Security Agency; (22) maintains CDC's emergency destruction plan for classified material and equipment; (23) conducts preliminary investigations of security violations relative to the loss or compromise/suspected compromise of sensitive, classified or crypto-logic materials or devices throughout CDC; (24) ensures proper destruction of classified documents that are no longer required; (25) conducts security inspections and audits of all national security information storage and processing areas; (26) responsible for implementing, maintaining, and updating of CDC Continuity Of Operations (COOP) communications vehicles; and (27) provides deployable unclassified and classified communication platforms to support high-level deploying staff to natural or manmade disaster areas in support of COOP plans.

Quality and Sustainability Office (CAJS15). (1) Provides quality assurance and continuous improvement by establishing a framework for process improvement associated with all OSSAM functions; (2) ensures accountability and environmental stewardship of agency assets in order to protect CDC's ability to carry out its health mission today and in the future; (3) conducts quality improvement audits on all OSSAM program areas of responsibility; (4) assembles technical advisory teams, as needed, to conduct audits/reviews of OSSAM program areas; and (5) provides oversight of CDC's sustainability programs.

Asset Management Services Office (CAJSB). The Asset Management Services Office (AMSO) provides a safe, secure, healthy, and functional workplace environment for CDC staff by ensuring that assets are managed effectively while maintaining efficient operations and logistical support, customer satisfaction, and environmental stewardship.

Office of the Director (CAJSB1). (1) Plans, directs, and coordinates the functions and activities of AMSO; (2) provides management and administrative direction for budget planning and execution, property management, and personnel management within AMSO; (3) provides leadership and strategic support to senior managers in the determination of CDC's long-term facility needs; (4) coordinates the operations of AMSO staff involved in the planning, evaluation, design, construction, and management of facilities and acquisition of property; (5) provides centralized value engineering services, policy development and coordination, and global acquisition planning for AMSO; (6) assists and advises senior CDC officials in the development, coordination, direction, and assessment of facilities and real property activities throughout CDC's facilities and operations, and assures consideration of facilities management implications in program decisions; (7) provides collaboration and centralized consolidation of division reporting requirements and other deliverables to the Department of Health and Human Services (DHHS), the Office of the Chief Financial Officer, and other internal and external entities; (8) oversees functions of the campus portfolio managers who prepare the capital and repair and improvements (R&D, CDC and HHS-level Facility Project Approval Agreements (FPAA), asset business plans, campus master plans, special studies, monitors performance indicators to identify/address portfolio deficiencies, serve on project core teams and administer the National Environmental Policy Act, Historic Preservation, Green Building, International Facilities, Real Property Acquisition, Asset Management Team and Security Liaison Activities.

Leased Property Management Services (CAJSB12). (1) Conducts real estate activities throughout CDC, including the acquisition of leased space, the purchase and disposal of real property for CDC nationwide (with emphasis on current and long-range planning for the utilization of existing and future real property resources); (2) performs space management (assignment and utilization) of all CDC space, both owned and leased, nationwide; (3) provides technical assistance in space planning to meet programmatic needs; (4) executes all easements for owned—in coordination with campus liaison officers—property; (5) administers day-to-day management of leased facilities and ensures contract compliance by lessors; (6) provides technical assistance and prepares contract specifications for all repair and improvement projects in leased space; (7) maintains liaison with the General Services Administration regional offices; (8) performs all functions relating to leasing and/or acquisition of real property under CDC delegation of authority for leasing, including direct lease actions; and (9) coordinates the relocation of CDC personnel within owned and leased space.

Engineering, Maintenance, and Operations Services Office (CAJSBB). The Engineering, Maintenance, and Operations Services Office (EMOSO) manages facilities engineering, engineering controls, security systems engineering, fire alarm and life safety, and monitors, operates, and maintains owned buildings, central utility plants, systems, equipment, and perform systems/building commissioning. Specifically, EMOSO: (1) Operates, maintains, repairs, and modifies CDC's

Atlanta-area office buildings, laboratories, and plant facilities and other designated CDC facilities throughout the United States (U.S.) and other geographic areas, and conducts a maintenance and repair program for CDC's program support equipment; (2) develops services for new, improved, and modified equipment to meet program needs; (3) provides technical assistance, reviews maintenance and operation programs, and recommends appropriate action for all Atlanta area facilities and other designated CDC facilities throughout the U.S. and other geographic areas; (4) provides recommendations, priorities, and services for new, improved, or modified equipment to meet program needs; (5) provides maintenance and operation of the central energy plant including structures, utilities production and distribution systems, and equipment; (6) conducts a program of custodial services, waste disposal, incinerations, disposal of biological waste, and other building services at all CDC Atlanta area facilities and other designated CDC facilities throughout the U.S. and other geographic areas; (7) provides landscape development, repair, and maintenance at all Atlanta area facilities and other designated CDC facilities throughout the U.S. and other geographic areas; (8) provides hauling and moving services for CDC in the Atlanta area; (9) provides an Integrated Pest Management Program to control insect and rodents for CDC in Atlanta area facilities; (10) develops required contractual services and provides supervision for work performed in these areas; (11) establishes and maintains a computerized system for maintenance services, for stocking and ordering supplies, and replacement parts; (12) provides for pick-up and delivery of supplies and replacement parts to work sites; (13) maintains adequate stock levels of supplies and replacement parts; (14) prepares design and contract specifications, and coordinates completion of contract maintenance projects; (15) manages CDC's Energy Conservation Program for all CDC facilities; (16) reviews all construction documents for energy conservation goals and compliance with applicable CDC construction standards; (17) participates on all core teams and value engineering teams; (18) provides maintenance and inspection for fire extinguishers and fire sprinkler systems; (19) provides services for the procurement of natural gas; (20) develops and maintains a standard equipment list for all CDC facilities; (21) assists the other AMSO offices with facility-related issues, as needed; (22) provides building coordinators to interface with program personnel to keep the building and equipment functioning; and (23) coordinates the commissioning of new buildings, structures, systems and components, as necessary.

Projects and Construction Management Services Office (CAJSBC). The Projects and Construction Management Services Office (PCMSO) manages capital improvement projects, repair and improvement projects, and construction services. Specifically, PCMSO: (1) Provides professional architectural/engineering capabilities, and technical and administrative project support to CDC and CIOs for renovations and improvements to CDC-owned facilities and construction of new facilities; (2) develops project management requirements (including determination of methods, means of project completion, and selection of resources); (3) provides critical path method scheduling support for all large capital construction projects and all R&I projects; and (4) provides central cost estimating support for all large capital construction projects, all R&I projects, special projects, feasibility studies, as requested, and certain work orders, as requested.

Logistics Management Services Office (CAJSBD). (1) Develops and implements CDC-wide policies, procedures, and criteria necessary to comply with federal and departmental regulations governing inventory management; property administration; property reutilization and disposal including chemical hazardous waste; supply management; and receiving and distribution; (2) determines, recommends, and implements procedural changes needed to maintain effective management of CDC property including but not limited to: inventory control; property records; and property reutilization and disposal; (3) provides audits, training and technical assistance to CDC CIOs on inventory management; property administration; property reutilization and disposal including chemical hazardous waste; supply management; and property receiving; (4) determines the requirement for and serves as the functional proponent for the design, test, and implementation of logistics management systems; (5) represents CDC on inter- and intra-departmental committees relevant to logistical functions; (6) serves as the CDC liaison to HHS and other federal agencies on logistical matters such as inventory management, property administration, property reutilization and disposal including chemical hazardous waste, supply management, and receiving and distribution; (7) functions as the CDC waste and recycling services manager; (8) provides medical maintenance management support for CDC's personal property; (9) provides logistics and movement planning support for CDC CIOs; and (10) establishes branch goals, objectives, priorities, and assures consistency and coordination with overall OSSAM logistical goals and objectives.

Design, Engineering and Management Services Office (CAJSBE). The Design, Engineering and Management Services Office (DEMSO) provides architectural, engineering design, project management services, and interior design services; and manages facility plans, drawings and technical documents and ensures proper configuration control. Specifically, DEMSO: (1) Prepares architectural and engineering designs, and specifications for construction of modifications and renovations to CDC-owned facilities; (2) provides architectural and engineering technical expertise and is the technical authority on new facilities, and modifications and renovations on facility project designs; (3) provides furniture, fixture, and equipment designs, and project management services for all CDC facilities; (4) provides record and guideline document support services to all AMSO offices; and (5) maintains CDC Design Standards and Guidelines for use as basis of design for construction of new facilities, and modifications and renovations in CDC-owned facilities.

Environment, Safety, and Health Compliance Office (CAJSC). The Environment, Safety, and Health Compliance Office (ESHCO) ensures compliance with applicable environment, safety and health regulations, empowers workers, and provides the tools needed for workers to be safe, work in a healthy environment, and ensures environmental stewardship. Specifically, ESHCO: (1) Provides leadership and service for the CDC Health and Safety Program to proactively ensure safe and healthy workplaces at CDC worksites for CDC employees, contractors, and visitors (including deployed personnel), and to protect the environment and communities adjacent to Atlanta area CDC-owned and leased facilities; (2) provides occupational health services to CDC staff through occupational health clinics at Atlanta area and Fort Collins and via contracts at other sites; (3) promotes healthy and safe work practices to prevent injury and illness; (4) provides advice and counsel to senior OD and CIO staff on health,

safety, and environment-related matters, and to individuals and organizations nationally and internationally; (5) provides advice, counsel, and direct support services to supervisors and employees on health, safety, and environment-related matters; (6) assures compliance with applicable federal, state, and local health, safety, and environmental (HSE) laws and regulations; (7) provides liaison with both CDC safety officers and staff, and other partners such as DHHS health and safety officials, Occupational Safety and Health Administration, Environmental Protection Agency, Nuclear Regulatory Commission, and other governmental and non-governmental organizations on HSE issues; (8) coproduces the CDC/National Institutes of Health publication, Biosafety in Microbiological and Biomedical Laboratories; (9) serves as a World Health Organization Collaborating Center for Applied Biosafety Programs and Training; (10) serves as a significant resource of subject matter expertise for the national and international community in the field of biosafety; and, (11) works with key partners, such as the World Health Organization, on critical health and safety issues around the globe.

Office of the Director (CAJSC1). (1) Serves as the principal advisor to the Director, OSSAM, with responsibility for the CDC Health and Safety Program; (2) plans, identifies, and requests required resources; directs, manages, and evaluates the operations and programs of ESHCO; (3) assures coordination and cooperation among ESHCO staff; (4) collaborates in the development and review of draft CDC policies to ensure compliance with applicable federal, state, and local HSE laws, regulations, and policies; (5) develops and implements new HSE injury/illness prevention programs indicated by surveys, incident investigations, reports of unsafe/unhealthful working conditions and other means; (6) assures cross-cutting, collaborative team functionality in building and maintaining a successful HSE program; (7) consults with individuals and organizations nationally and internationally on issues such as laboratory safety, biosafety, occupational health issues in the biomedical laboratory and animal care setting, and deployment health and safety; (8) maintains oversight and support for the CDC HSE committees in operational components with representation, attendance, interaction and collaboration, and collaboration with non-Atlanta health and safety officers and staff; and (9) provides an annual report on the CDC HSE and other reports required or requested by CDC management officials, HHS, and regulatory agencies.

WorkLife Wellness Office (CAJSD). The WorkLife Wellness Office (W2O) provides an environment that promotes a culture that improves the health and resilience of workers by integrating effective policies, programs, and processes accessible to all staff to sustain and improve performance, increase readiness, and support healthy choices and behaviors. Specifically, W2O: (1) Provides a core set of services and resources related to resilience and readiness including preventive screenings, wellness-enhancing activities, health education, counseling and follow-up care/referrals; (2) engages in holistic organizational wellness efforts such as benchmarking best practices, implementing or maintaining proper policy, systems, linkages, physical environment, social environment, and external partners/coalitions outreach; (3) oversees the lifestyle fitness centers; (4) directs the employee assistance program; and (5) manages the vending/cafeteria services.

Security Services Office (CAJSE). The Security Services Office (SSO) serves as the lead organizational entity for providing the overall framework, direction, coordination, implementation, oversight and accountability for CDC's infrastructure protection, and personnel security program. SSO serves as the primary liaison for homeland security activities; provides a secure work environment for CDC/ATSDR personnel, visitors and contractors; and plans and implements the agency's crisis management activities which ensure a continued public health response to the nation.

Office of the Director (CAJSE1). (1) Directs, manages, coordinates and evaluates the programs and activities of the SSO; (2) develops goals and objectives and provides leadership, policy formulation and guidance in program planning and development; (3) prepares, reviews, and coordinates budgetary, informational, and programmatic documents; (4) provides oversight and comprehensive security services to CDC's Strategic National Stockpile program; and (5) serves as a liaison to local, state, and federal law enforcement entities and security personnel within other HHS Operating Divisions.

Physical Security Laboratory and Technical Branch (CAJSEB). (1) Provides coordination, guidance, and security operations to all facilities CDC-wide including all owned and leased sites; (2) provides campus-wide access control for all the Atlanta leased sites; the Chamblee and Lawrenceville campuses; Anchorage, Alaska; and Fort Collins, Colorado; and all other CDC laboratories; (3) provides management and oversight of contract guard force and local police; (4) responsible for physical security during emergency operations; (5) promotes theft prevention, provides training and conducts investigations; (6) conducts site surveys to assess all physical security activities and correct deficiencies and implement improvement as necessary; (7) provides leadership and coordination in planning and implementation for internal emergency; (8) manages and maintains the emergency alert system; (9) maintains 24-hour emergency notification procedures for Fort Collins, Colorado; San Juan, Puerto Rico; and Anchorage, Alaska; and (10) manages and operates CDC's Security Operations Centers (SOC) 24 hours a day, seven days a week at the Roybal campus, Fort Collins, and other sites as constructed; (11) manages the Locksmith Office; (12) maintains inventory controls and measures and implements, installs, repairs, and re-keys all locks with emphasis on the overall physical security of CDC and its owned and leased facilities; (13) provides security recommendations to CDC programs regarding capabilities and limitations of locking devices; (14) provides combination change services to organizations equipped with cipher locking devices; (15) coordinates with engineers and architects on CDC lock and keying requirements for new construction (16) improves and expands video monitoring to ensure the security of all employees, visitors, contractors and the general public while at the CDC; (17) manages and coordinates Select Agent security and the CDC Safety and Security Plan; (18) manages and maintains the Intrusion Detection Automated system, including P2000, and; (19) provides coordination, guidance, and security operations for all CDC laboratories nationwide.

Physical Security Operations Branch (CAJSEC). The Physical Security Operations Branch (PSOB) coordinates and implements security operations, including access control and crisis management, for the CDC Headquarters campus and directs and oversees the security guard contract for Atlanta facilities. Specifically, PSOB: (1) Provides coordination, guidance, and security operations; (2) provides campus-wide access control; (3) provides management and oversight of

contract guard force and local police; (4) conducts physical security during emergency operations; (5) promotes theft prevention, provides training and conducts investigations; (6) conducts site surveys to assess all physical security activities and correct deficiencies and implement improvement as necessary; (7) manages and operates CDC's Security Operations Centers (SOC) 24 hours a day, seven days a week at the Roybal campus, and other sites as constructed; (8) coordinates nationwide security operations through the Roybal campus SOC (9) maintains 24-hour emergency notification procedures; (10) manages and maintains the emergency alert system; (11) provides leadership and coordination in planning and implementation for internal emergency incidents affecting the Roybal campus, including incident response and incident support; (12) improves and expands video monitoring to ensure the security of all employees, visitors, contractors and the general public while at the CDC; (13) provides coordination, guidance, and security operations for all Global Communication Center events and visits; (14) manages and coordinates the security of all visitors and guests to all Atlanta-area CDC campuses.

Personnel Security Branch (CAJSED). (1) Conducts background investigations and personnel suitability adjudications for employment with CDC in accordance with 5 CFR part 731, Executive Order 12968 and Executive Order 10450; (2) submits documentation for security clearances, and maintains an access roster in a security clearance database; (3) implements high risk investigations such as Public Trust Investigations for employees GS–13s and above who meet Department of Health and Human Services criteria standards for employees working in Public Trust positions; (4) conducts adjudications for National Agency Check with Inquiries (NACI) cases and assists DHHS in adjudicating security clearance cases; (5) provides personnel security services for full time employees, guest researchers, visiting scientists, students, contract employees, fellows, and the commissioned corps; (6) conducts initial ''Security Education Briefing'' and annual Operational Security Training; (7) coordinates employee drug testing; (8) provides identification badges and cardkey access for personnel within all CDC metro Atlanta area facilities as well as some out-of-state CDC campuses; (9) enrolls individuals with a security clearance or approval in the biometric encoding system; (10) maintains hard copy records of all individuals' requests and authorizations for access control readers; and (11) manages and operates cardkey systems.

Transportation Services Office (CAJSG). The Transportation Services Office (TSO) develops and provides CDC-wide transportation policies, procedures and services ensuring a safe, secure and healthy workplace is established and maintained in accordance with federal and departmental regulations. Specifically, TSO: (1) Provides oversight, expertise, guidance, and program support for transportation related activities; (2) provides subject matter expertise on transit initiatives, facility master planning, and liaise with the community regarding transportation planning; (3) provides fleet management and shipping operations; (4) performs parking administration, commuter assistance, manages the Transportation Choices Program, employee housing and relocation services, and coordinates transportation services; (5) develops and implements CDC-wide policies, procedures, and criteria necessary to comply with federal and departmental regulations governing transportation and fleet management; (6) determines, recommends, and implements procedural changes needed to maintain effective management of CDC transportation services including but not limited to: shipping and return of CDC materiel; transportation of freight; and CDC's vehicle fleet; (7) represents CDC on inter- and intra-departmental committees relevant to transportation and traffic management; and (8) establishes branch goals, objectives, and priorities, and assures consistency and coordination with overall OS SAM goals and objectives.

Dated: April 26, 2013.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2013–11142 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 25743–25746, dated May 2, 2013) is amended to reorganize the Office of the Associate Director for Communication, Office of the Director, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the titles and functional statements for the Office of the Associate Director for Communication (CAU) and insert the following:

The mission of the Office of the Associate Director for Communication (OADC) is to further customer-centered, science-based and effective communication to support the Centers for Disease Control and Prevention's (CDC) public health work. In carrying out its mission, the OADC: (1) Serves as a communication advisor and strategist to CDC's Director and senior leadership; (2) conducts and promotes health communication science practices to address agency priorities; (3) provides communication services including broadcast, CDC–INFO, graphics, translation, interpretation and photography; (4) promotes open and clear employee communication; and (5) develops, guides, and implements internal and external public affairs strategies and activities.

Office of the Director (CAU1). (1) Manages, directs, and evaluates activities of the OADC; (2) makes sure CDC communication activities comply with Department of Health and Human Services (HHS) established policies; (3) communicates the value and benefits of CDC programs; (4) leads strategic communication activities addressing agency-wide priorities; (5) provides strategic communication support for CDC's emergency responses and the Joint Information Center; (6) provides reputation management expertise and counsel; (7) provides leadership and guidance to communicate decisions made by CDC's leadership in an efficient and clear manner; (8) coordinates with Centers/Institute/Offices (CIOs) on communication activities; (9) provides leadership and guidance to manage and operate OADC's programs including the areas of fiscal management, personnel, travel, and other administrative services; (10) develops and tracks OADC's annual budget and spending plan to fulfill CDC's communication priorities; (11) serves as OADC's primary point of contact with CDC's Procurement and Grants Office and Office of the Chief Financial Officer on contracts and

budget matters; and (12) ensures all communication products authored by CDC staff members or published by CDC are released for public use in a timely manner, are of the highest quality and are scientifically sound, understandable, and useful to the intended audience.

Office of Communication Science (CAU13). (1) Serves as the principal advisor on the scientific basis for communication and marketing practice; (2) guides CIOs on applying measures of effectiveness for public health communication efforts; (3) guides, advises and trains on plain language to make CDC health information accessible and understandable to audiences that may have specific health literacy needs; (4) provides implementation for the Plain Writing Act; (5) distributes health communication and marketing research to interested professionals at CDC, its partners, and other stakeholders; and (6) manages clearances of CDC's communication materials for the public with HHS and the Office of Management and Budget.

Division of Public Affairs (CAUB). (1) Provides implementation and evaluation of public affairs, news and digital media, and employee communication throughout CDC; (2) plans and designs digital media to distribute public health information to the public, including Web sites, usability testing, and mobile applications; (3) provides leadership and management of CDC's Web site (*www.cdc.gov*); (4) provides content, policy review, and clearance of news media materials with HHS, including press releases, press kits, talking points, letters to editors, and fact sheets; (5) manages and responds to news media requests for access to CDC, its subject matter experts, reports, and publications; (6) provides leadership and guidance for external public relations strategies; (7) develops communication strategies to communicate with the agency's workforce; and (8) provides agency-wide leadership, technical assistance, and consultation in risk communication and reputational management.

Office of the Director (CAUB1). (1) Develops the strategic priorities and manages the program activities of the division; (2) leads the agency's news and electronic media activities; (3) provides guidance and recommendations on effective use of news and digital media to CDC's director, leadership, and CIOs; (4) collaborates and coordinates with other federal organizations and external stakeholders on news and digital media; and (5) serves as liaison on news and digital media policies, procedures, and clearances to HHS' Office of Assistant Secretary for Public Affairs.

Digital Media Branch (CAUBB). (1) Leads the selection, design, development, and evaluation of digital media technologies; (2) leads and manages CDC's digital communications systems and architectures for Web, Intranet, mobile sites and applications, and social media (i.e., Web Content Management System, mobile services, CDC.gov servers, search engine, content syndication); (3) provides operations support and management for CDC's Web site, Intranet Web sites, and CDC's main social media channels, including CDC.gov top tier, CDC en Espanol, mobile apps, and CDC Connects; (4) coordinates the CDC.gov and social media governing bodies (Web Council, Social Media Council, and related Communities of Practice and workgroups); (5) works with other federal organizations to develop tools and systems, coordinate digital media strategies, conduct research on digital user experiences, and reviews communication technology; (6) supports online collaborations with internal and external partners; and (7) collects and analyzes CDC Web user data/metrics to assess health impact, usability, and accessibility.

News Media Branch (CAUBC). (1) Provides leadership in the development and use of news media strategies and practices; (2) obtains HHS clearance of news media materials for media outlets and the public (press releases, press kits, talking points, letters to editors, and fact sheets); (3) promotes health information to the public through news media channels; (4) manages and responds to news media requests for access to CDC subject matter experts, reports, and publications; (5) works with CDC's CIOs to identify news media opportunities and responds to issues that arise; (6) provides news media/spokesperson training and technical assistance to CDC staff; and (7) develops and supports long lead media opportunities and responds to requests.

External and Employee Relations Branch (CAUBD). (1) Creates recognized employee communication system to increase clear communication between CDC leadership and employees, and across employee groups, including CDC Connects and other employee information channels; (2) manages CDC's scientific museum and learning center, the David J. Sencer CDC Museum; (3) implements strategies to communicate with CDC customers, partners and stakeholders, including Director's All Hands and Speakers' Bureau; (4) creates and implements employee communication special activities; (5) serves as the central point of contact for CDC Office of the Director announcements; and (6) serves as liaison to provide agency communication to former employees and retirees.

Division of Communication Services (CAUD). The Division of Communication Services (DCS) provides agency-wide CDC graphics, broadcast, photography, translation, interpretation and sign language, public information, and communication consultation/analysis leadership and support. To carry out its mission, the division performs the following functions: (1) Ensures broadcast functionality/broadcast engineering support including connectivity among physical assets such as the Global Communications Center, Emergency Operations Center, and continuity of operations for CDC; (2) develops and disseminates video and audio production; (3) manages CDC graphic design and production services including CDC branding and identity standards; (4) supports new broadcast communication mechanisms (e.g. HHS TV, CDC TV, radio/TV broadcast, podcast, webcast, and videos-on-demand) for CDC programs; (5) provides support for broadcast delivery press conferences and media interviews; (6) provides scientific and events photography; (7) provides multilingual translation and interpretation, sign language support, and cross cultural communication assistance to CIOs across CDC; (8) provides consultation and analysis of consumer research data to CIOs used for developing and evaluating health communication and marketing to specific audiences; (9) manages day-to-day operations of meeting space within CDC's meeting center, the Global Communications Center; and (10) manages CDC–INFO (CDC's telephone, email, and publications fulfillment services center).

Office of the Director (CAUD1). (1) Develops the strategic priorities and manages the program activities of the division; (2) provides leadership for ensuring all DCS products are of the highest quality; (3) helps CIOs use existing or develop new mechanisms for communicating with the public and CDC partners; (4) coordinates support for meetings held in the Global Communications Center with internal and external customers; (5) coordinates the use of the CDC exhibit for public health conferences; (6) manages overall IT-related functions for the division, including Create-IT (DCS' online internal tracking and triage system), Trados SDL (translation memory application), and CDC–INFO IT

applications; (7) provides and manages multi-year, multi-vendor CDC-wide communication contracts mechanism for use by CIO clients; and (8) updates and manages Create-IT system for tracking and triage of work requests including associated customer satisfaction and other performance metrics for internal and external (CIO) use.

CDC–INFO (CAUD12). (1) Provides the public with accessible, accurate, and credible health information in English and Spanish, 24/7, to include phone, email and U.S. mail; (2) ensures the CDC–INFO call center standards are kept for quality assurance, customer satisfaction, performance, and health impact when dealing with the public; (3) provides surge (to include 24/7) support through the 1–800 call center for public health emergencies and establishes policies and procedures with the CDC Emergency Operations Center, Joint Information Center; (4) manages CDC's ordering and distribution facility for health publications; and (5) analyzes and reports CDC–INFO data to inform communication planning and programs throughout the agency.

Broadcast Services Branch (CAUDB). (1) Develops and produces audio, video, and multi-media health information products; (2) provides CDC with global communication capacity for high-definition broadcast, webcast and emerging social and health media delivery channels; (3) supports the CDC Emergency Operations Center to provide response capacity and capability for emergency broadcasts; (4) develops and delivers health information broadcast programs in coordination with HHS for the public, including podcasts, CDC–TV and other channels; (5) creates and produces communication using new forms of social and electronic media; (6) collaborates with other areas of CDC to review and recommend potential audio and video technology; and (7) develops distance education, health communication, and training products to reach public health partners and professionals.

Graphics Services Branch (CAUDC). (1) Leads and coordinates CDC visual information activities; (2) develops and produces graphic illustrations, including scientific posters, infographics, desktop published documents, visual presentations, conference materials, brochures and fact sheets, newsletters, and exhibits; (3) manages scientific and event photography; and (4) provides creative direction and brand management guidance for graphics products and sets guidelines and standards for quality and consistency across the agency.

Strategic and Proactive Communications Branch (CAUDD). (1) Provides technical assistance on large or multidisciplinary projects to provide a consistent approach across communication products; (2) administers CDC wide multi-year, multi-vendor communication contracts mechanism; (3) advises on methods for gaining public input on health issues and priorities (e.g., advisory mechanisms, focus groups, polling, legislative, and media tracking); (4) manages contract resources and provides analysis relative to audience segmentation and behavior; (5) consults with CDC programs on ways to utilize predictive analytics and other tools to facilitate targeted program application and/or measurement of program effectiveness; (6) provides consultation for strategic communication implementation and applying health communication and social marketing techniques both internally and externally; (7) provides agency-wide multi-lingual service (MLS) support to include direct Spanish language translation, facilitating and coordinating support for other languages, and cross-cultural communication assistance as well as MLS leadership (e.g. implementation of agency Language Access Plan); and (8) assists in planning and management of video challenges.

Dated: April 17, 2013.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2013–11143 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 25743–25746, dated May 2, 2013) is amended to reorganize the National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the titles and functional statements for the Influenza Division (CVGD) and insert the following:

Influenza Division (CVGD). The Influenza Division (ID) improves global control and prevention of seasonal and novel influenza and improves influenza pandemic preparedness and response. In collaboration with domestic and global partners, the ID: (1) builds surveillance and response capacity; (2) monitors and assesses influenza viruses and illness; (3) improves vaccines and other interventions; and (4) applies research to provide science-based enhancement of prevention and control policies and programs.

Office of the Director (CVGD1). (1) Provides vision, leadership and direction for the division; (2) fosters external partnerships and cross-cutting activities that support quality science and strong global partnerships; (3) provides leadership and guidance in policy formulation; (4) provides support for national and international capacity building programs; (5) provides technical expertise and leadership for national and international pandemic preparedness activities; and (6) provides technical expertise for communications, information technology, genomic sequencing, and reagent resources.

Virology, Surveillance and Diagnosis Branch (CVGDB). (1) Conducts comprehensive antigenic, phenotypic, genotypic, structural, and evolutionary characterization of human and animal influenza viruses; (2) performs genetic and antigenic pandemic risk assessment of novel influenza viruses; (3) develops and evaluates novel and seasonal candidate vaccine viruses; (4) provides expert guidance on influenza vaccine virus selection; (5) develops methods to detect and characterize influenza viruses; and (6) trains and supports laboratories that perform influenza testing.

Epidemiology and Prevention Branch (CVGDC). (1) Conducts surveillance and research activities to better understand the epidemiology of influenza; and (2) improves understanding of the effectiveness of influenza antiviral and vaccine programs.

Immunology and Pathogenesis Branch (CVGDE). (1) Increases knowledge and improves understanding of immunity and immune correlates of protection; (2) develops and improves vaccines; (3) determines virus and host factors that impact virulence and transmission of influenza viruses; (4) conducts immunologic and virologic pandemic risk assessment of novel influenza viruses; and (5) trains and supports

laboratories that perform immunologic testing.

Dated: May 2, 2013.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2013–11144 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–64, CMS–1957, and CMS–10169]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Indirect Medical Education (IME) and Supporting Regulations at 42 CFR 412.105; Direct Graduate Medical Education (GME) and Supporting Regulations at 412 CFR 413.75 through 83; *Use:* Section 1886(d)(5)(B) of the Social Security Act (the Act) requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2011, the estimated Medicare program payments for indirect medical education (IME) costs amounted to $6.59 billion. Medicare program payments for direct graduate medical education (GME) are also based upon the number of FTE–IRs that work at a hospital. In FY 2011, the estimated Medicare program payments for GME costs amounted to $2.57 billion. *Form Number:* CMS–R–64 (OCN: 0938–0456); *Frequency:* Reporting—Annually; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,075; *Total Annual Responses:* 1,075; *Total Annual Hours:* 2,150. (For policy questions regarding this collection contact Milton Jacobson at 410–786–7553. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Social Security Office (SSO) Report of State Buy-in Problem; *Use:* Under Section 1843 of the Social Security Act, states may enter into an agreement with the Department of Health and Human Services to enroll eligible individuals in Medicare and pay their premiums. The purpose of the State Buy-in program is to assure that Medicaid is the payer of last resort by permitting a state to provide Medicare protection to certain groups of needy individuals, as part of the state's total assistance plan. State Buy-in also has the effect of transferring some medical costs for this population from the Medicaid program, which is partially state funded to the Medicare program, which is funded by the federal government and individual premiums. Generally, the States Buy-in for individuals who meet the eligibility requirements for Medicare and are cash recipients or deemed cash recipients or categorically needy under Medicaid. In some cases, states may also include individuals who are not cash assistance recipients under the Medical Assistance Only group. The day-to-day operations of the State Buy-in program is accomplished through an automated data exchange process. The automated data exchange process is used to exchange Medicare and Buy-in entitlement information between the Social Security District Offices, Medicaid State Agencies and the Centers for Medicare & Medicaid Services. When problems arise however that cannot be resolved though the normal data exchange process, clerical actions are required. The CMS–1957, ''SSO Report of State Buy-In Problem'' is used to report Buy-in problems cases. The CMS–1957 is the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. *Form Number:* CMS–1957 (OCN: 0938–0035); *Frequency:* Reporting—Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 3,802; *Total Annual Responses:* 3,802; *Total Annual Hours:* 1,266. (For policy questions regarding this collection contact Lucia Diaz-Robinson at 410–247–6843. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program. *Use:* Since 1989, Medicare has been paying for durable medical equipment (DME) and supplies (other than customized items) using fee schedule amounts that are calculated for each item or category of DME identified by a Healthcare Common Procedure Coding System code. Payments are based on the average supplier charges on Medicare claims from 1986 and 1987 and are updated annually on a factor legislated by Congress. For many years, the Government Accountability Office and the Office of Inspector General of the U.S. Department of Health and Human Services have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DME. Due to reports of Medicare overpayment of DME and supplies, Congress required that CMS conduct a competitive bidding demonstration project for these items. Accordingly, CMS implemented a demonstration project for this program from 1999–2002 which produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. Shortly after a successful demonstration of the competitive bidding program, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and mandated a phased-in approach to implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). The statute

specifically required the Secretary to establish and implement programs under which competitive bidding areas are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the ''Medicare DMEPOS Competitive Bidding Program.''

CMS conducted its first round of bidding for the Medicare DMEPOS Competitive Bidding Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor. CMS published a Request for Bids instructions and accompanying forms for suppliers to submit their bids to participate in the program. During this first round of bidding, DMEPOS suppliers from across the U.S. submitted bids identifying the MSA(s) to service and the competitively bid item(s) they wished to furnish to Medicare beneficiaries. CMS evaluated these bids and contracted with those suppliers that met all program requirements. The first round of bidding was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed this program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the competitive bidding program which included, but are not limited to: a delay of Rounds 1 (competition began in 2009) and 2 of the program (competition began in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy from Round 1 and group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to suppliers regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of the MIPPA specified that the competition for national mail order items and services may be phased in after 2010 and established a rule requiring that a bidder demonstrate that its bid covers 50 percent (or higher) of the types of diabetic testing strips, based on volume (the ''50 percent rule'') for national mail order competitions. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011.

The Affordable Care Act, enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a competition for National Mail Order of Diabetic Testing Supplies at the same time as Round 2. The Round 2 and National Mail-Order contracts and prices have a target implementation date of July 1, 2013.

The MMA requires the Secretary to re-compete contracts not less often than once every 3 years. Most Round 1 Rebid contracts will expire on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetic testing supplies ended on December 31, 2012.) Consequently, we are currently in the process of re-competing the competitive bidding contracts in the Round 1 Rebid areas.

The most recent approval for this information collection request (ICR) was issued by OMB on October 10, 2012. Since then, CMS has decided to sequentially update the paperwork burden necessary to administer the program as it expands nationally and cycles through multiple rounds of competition. Specifically, we are now seeking to update our burden estimates for certain contract maintenance forms for Round 2 and the national mail-order competitions. These include Form C and the Contract Supplier's Disclosure of Subcontractors form. We are also requesting approval of two additional forms: the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, which will be utilized in all rounds of competition. Finally, we are retaining without change Forms A, B, and D and their associated burden under this ICR. We note that the information collection for Forms A and B is already complete. We intend to continue use of the forms in future rounds of competition.

Form Number: CMS–10169 (OCN: 0938–1016). *Frequency:* Occasionally. *Affected Public:* Private Sector (business or other for-profits) and Individuals or households. *Number of Respondents:* 19,035. *Total Annual Responses:* 19,035. *Total Annual Hours:* 9,311. (For policy questions regarding this collection contact Michael Keane at 410–786–4495. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on June 10, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer. Fax Number: (202) 395–6974. Email: *OIRA_submission@omb.eop.gov*.

Dated: May 6, 2013.

Martique Jones,

Deputy Director, Regulations Development Group,Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–11033 Filed 5–9–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–70, CMS–R–72, CMS–R–247, CMS–10287, CMS–R–43, CMS–855(POH), CMS–2552–10, and CMS–10062]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

1. *Type of Information Collection Request:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations in 42 CFR, Sections 480.104, 480.105, 480.116, and 480.134; *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations

(QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment.: *Form Number:* CMS–R–70 (OCN: 0938–0426); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profits; *Number of Respondents:* 400; *Total Annual Responses:* 21,200; *Total Annual Hours:* 42,400. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements at 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are imposed on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. *Form Number:* CMS–R–72 (OCN: 0938–0443); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 2,590; *Total Annual Responses:* 5,228; *Total Annual Hours:* 2,822. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations Contained in 42 CFR 410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63; *Use:* According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro- and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. Despite this knowledge, diabetes remains the leading cause of blindness, lower extremity amputations and kidney disease requiring dialysis. Diabetes and its complications are primary or secondary factors in an estimated 9 percent of hospitalizations (Aubert, RE, et al., Diabetes-related hospitalizations and hospital utilization. In: Diabetes in America. 2nd ed. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, NIH, Pub. No 95–1468–1995: 553–570). Overall, beneficiaries with diabetes are hospitalized 1.5 times more often than beneficiaries without diabetes. HCFA–3002–F ''Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements'', provided for uniform coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified non-physician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. This rule established the quality standards that an entity would be required to meet in order to participate in furnishing diabetes outpatient self-management training services. It set forth payment amounts that have been established in consultation with appropriate diabetes organizations. It implements section 4105 of the Balanced Budget Act of 1997. *Form Number:* CMS–R–247 (OCN: 0938–0818); *Frequency:* Recordkeeping and Reporting—Occasionally; *Affected Public:* Business or other for-profit institutions; *Number of Respondents:* 5327; *Total Annual Responses:* 63,924; *Total Annual Hours:* 197,542. (For policy questions regarding this collection contact Kristin Shifflett at 410–786–4133. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Quality of Care Complaint Form; *Use:* In accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) are required to conduct appropriate reviews of all written complaints submitted by beneficiaries concerning the quality of care received. The Medicare Quality of Care Complaint Form will be used by Medicare beneficiaries to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure pertinent information is obtained by QIOs to effectively process these complaints. *Form Number:* CMS–10287 (OCN: 0938–1102); *Frequency:* Reporting—Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,500; *Total Annual Responses:* 3,500; *Total Annual Hours:* 583. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Portable X-ray Suppliers and Supporting Regulations in 42 CFR Sections 486.104, 486.106, 486.110; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. These conditions are based on a provision specified in law relating to diagnostic X-ray tests ''furnished in a place of residence used as the patient's home,'' and are designed to ensure that each supplier has a properly trained staff to provide the appropriate type and level of care, as well as, a safe physical environment for patients. CMS uses these conditions to certify suppliers of portable X-ray services wishing to participate in the Medicare program. This is standard medical practice and is necessary in order to help to ensure the well-being, safety and quality professional medical treatment accountability for each patient. *Form Number:* CMS–R–43 (OCN: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 578; *Total Annual Responses:* 578; *Total Annual Hours:* 948. (For policy questions regarding this collections contact Alesia Hovatter at 410–786–6861. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Annual Report of Physician-Owned Hospital Ownership and/or Investment Interest; *Use:* Section 6001 of the Affordable Care Act (ACA) requires Medicare hospitals to report whether they have any physician owners including immediately family members of the physician.

Currently the CMS 855A captures basic ownership/managerial information on providers. The CMS 855A was revised in July 2011 and a specific attachment designed to capture physician-owned hospital ownership and investment interest data was added to the form. The attachment is being removed from the CMS 855A application because the annual reporting requirement for physician-owned hospitals is not required for Medicare enrollment processing. This physician-owned hospital data collection is mandated to be reported on an annual basis. Additionally, the ACA prohibits the expansion of current physician-owned hospitals and banned the establishment of new ones making the CMS 855A the improper method to collect this required annual report.

CMS is requesting the physician-owned hospital ownership information, investment information or both, previously collected in Attachment 1 of the CMS 855A enrollment application to become a stand-alone form with a unique OMB number for the following reasons:

- The physician-owned data collection has a small targeted audience of approximately 140 physician-owned hospitals nationwide.
- The physician-owned data collection is required annually, as noted above.
- The data required under section 6001 is more specific than the data currently collected on the CMS–855A provider enrollment application.
- The data is not required for Medicare provider enrollment purposes.

Form Number: CMS–855 (POH)(OCN: 0938-New); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 140; *Total Annual Responses:* 140; *Total Annual Hours:* 140. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Health Care Complexes and Supporting Regulations in 42 CFR 413.20 and 413.24; *Use:* Medicare Part A institutional providers must provide adequate cost data to receive Medicare reimbursement (42 CFR 413.24(a)). Providers must submit the cost data to their Medicare Fiscal Intermediary (FI)/Medicare Administrative Contractor (MAC) through the Medicare cost report (MCR). We are submitting a revision of the Hospital and Hospital Health Care Complex Cost Report, Form CMS–2552–10. Form CMS 2552–10 is used by hospitals participating in the Medicare program to report the health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. The revisions were caused by legislative requirements in the Patient Protection and Affordable Care Act of 2010 and the Temporary Payroll Tax Cut Continuation Act of 2011. *Form Number:* CMS–2552–10 (OCN: 0938–0050); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 6,171; *Total Annual Responses:* 6,171; *Total Annual Hours:* 4,153,083. (For policy questions regarding this collection contact Nadia Massuda at 410–786–5834. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection. *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments. *Use:* CMS will use the data to make risk adjusted payment under Parts C. MA and MA–PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS–HCC and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. *Form Number:* CMS–10062 (OMB 0938–0838). *Frequency:* Quarterly. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 766. *Total Annual Responses:* 830,000. *Total Annual Hours:* 40,650. (For policy questions regarding this collection contact Michael Massimini at 410–786–1566. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by July 9, 2013:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 6, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–11035 Filed 5–9–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 10, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0337. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill Licensing Application—21 CFR Part 515 (OMB Control Number 0910–0337)—Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at 21 CFR part 515.

In the **Federal Register** of December 21, 2012 (77 FR 75635), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was unrelated to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated Feed Mill License Application Using Form FDA 3448 (515.10(b)).	20	1	20	0.25 (15 minutes)	5
Supplemental Feed Mill License Application Using Form FDA 3448 (515.11(b)).	40	1	40	0.25 (15 minutes)	10
Voluntary Revocation of Medicated Feed Mill License (515.23).	40	1	40	0.25 (15 minutes)	10
Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c)).	1	1	1	4	4
Total					29

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	No. of recordkeepers	No. of responses per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Labeling (510.305).	950	1	950	0.03 (2 minutes)	28.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimated annual reporting burden on industry is 29 hours as shown in table 1. Industry estimates it takes about 15 minutes (0.25) to submit the application. We estimate 100 original and supplemental applications, and voluntary revocations for a total of 25 hours (100 submissions x 0.25 (15 minutes)). An additional 4 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 28.5 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated 2 minutes (0.03 hour) for each of approximately 950 licensees. Total burden for reporting and recordkeeping would be 57.5 hours.

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11126 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 5, 2012, the Agency submitted a proposed collection of information entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0726. The approval expires on December 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11128 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0560]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 11, 2013, the Agency submitted a proposed collection of information entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0582. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11125 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0523]

Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the requirements for reporting information about authorized generic drugs in an annual report.

DATES: Submit either electronic or written comments on the collection of information by *July 9, 2013.*

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information 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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–

400B, Rockville, MD 20857, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910–0646)—Extension

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required, under § 314.81(b)(2)(ii)(*b*) (21 CFR 314.81(b)(2)(ii)(*b*)), the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act (Public Law 110–85), which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

Based on the number of annual reports the Agency currently receives under § 314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

FDA estimates the burden of this collection of information is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.81(b)(2)(ii)(*b*)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of authorized generic drug information in each annual report.	70	7	490	0.5 (30 minutes)	245
Submission of authorized generic drug information on first marketed generics in an annual report.	20	1	20	1	20
Submission of a copy of that portion of each annual report containing authorized generic drug information.	70	7	490	0.05 (3 minutes)	25
Total					290

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11127 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Analgesic Drug Products Advisory Committee.

General Function of the Committee: To provide advice and

recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on July 18, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AADPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On July 18, 2013, the committee will discuss new drug application (NDA) 022225, sugammadex sodium injection, submitted by Organon USA Inc., for the proposed indications of routine reversal of moderate and deep neuromuscular blockade (NMB) induced by rocuronium or vecuronium and immediate reversal of NMB at 3 minutes after administration of rocuronium.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 3, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 25, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 26, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11133 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. 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 Reports Clearance Officer at (301) 443–1984.

HRSA especially 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.

Information Collection Request Title: Develop and Implement UCARE4LIFE Message Library (OMB No. 0915–xxxx)—New

Abstract: HRSA HIV/AIDS Bureau (HAB) will develop and implement the UCARE4LIFE message library project aimed at increasing HIV primary care retention rates for racial and ethnic minority youth aged 15 to 24 living with HIV/AIDS. The primary aims are: (1) to develop, test, and maintain a text message library, which addresses topics of HIV disease management, e.g. appointment keeping, retention in care, and medication adherence rates; and (2) to develop, implement, conduct, and evaluate a pilot study of delivering text messages to targeted youth receiving care at Ryan White grantee sites and other clinical sites. HRSA awarded a two-year contract to the Research Triangle Institute (RTI) International to conduct the UCARE4Life project. The UCARE4Life project is supported by the Department of Health and Human

Services Secretary's Minority AIDS Initiative Fund (SMAIF), fiscal year (FY) 2012 and FY2013 and a gift from the M.A.C. AIDS Fund.

The first phase of this project will include focus group interviews with the target audience to test the messages (Aim 1). Approximately 128 individuals will be screened to assess focus group eligibility. Four focus groups will be conducted with up to eight participants in each for a total sample size of 32.

The second phase of this project involves the evaluation of the pilot study (Aim 2). This will encompass data collection with patients and providers. Patient participants for the pilot study will be recruited from 10 clinical sites, some of which will be Ryan White grantees. Up to 1,000 individuals will be screened to determine eligibility for the pilot study to recruit a sample of 500 participants (50 from each clinical site). Participants will complete a baseline survey, 3-month survey, 6-month survey, and follow-up survey at 9 months. In addition, 10 patient participants from each clinical site will be selected to participate in an in-depth, qualitative telephone interview for a total of 100 interviews. Finally, up to three clinic staff from the 10 participating clinics will take part in in-depth, qualitative telephone interviews (N=30).

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.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Patient focus group screener	128	1	128	0.25	32
Patient Focus Group Interview	32	1	32	2.00	64
Patient Pilot Study Screener	1,000	1	1,000	0.25	250
Patient Pilot Study Surveys	500	4	2,000	0.75	1,500
Patient Pilot Study Qualitative Interviews	100	1	100	1.00	100
Clinic Staff Pilot Study Qualitative Interviews	30	1	30	0.75	22.5
Total	1,790		3,290		1,968.5

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.

Deadline: Comments on this information collection request must be received within 60 days of this notice.

Dated: May 3, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–11092 Filed 5–9–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Date and Time: May 30, 2013, 10:00 a.m.–5:00 p.m. Eastern Time.

Place: Webinar format.

Status: The meeting will be open to the public.

Purpose: The Council on Graduate Medical Education provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs.

At this meeting, the Council will finalize work on its 21st Report and then begin discussions for its next report. The Council will also discuss recent developments in the physician workforce and in graduate medical education.

Agenda: The meeting on Thursday, May 30, 2013, will begin with opening comments from HRSA senior officials. Work on the Council's 21st report on the restructuring of graduate medical education will finish. The Council will also discuss current issues related to the physician workforce and graduate medical education with the objective of determining a topic for the next report. The Council will plan for its next meeting, which will be face-to-face, for late summer of 2013. An opportunity will be provided for public comment at the end of the meeting.

SUPPLEMENTARY INFORMATION: Information on accessing the webinar will be available via the following Web site two days prior the meeting date: *http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html.* The audio portion of the meeting will be computer-based; therefore, anyone wishing to make a public comment should use the Question & Answer Pod anytime during the meeting. The questions will be collected and as many addressed as possible during time provided at the end of the meeting. Anyone wishing further information on the webinar aspects of the meeting should contact Iwona Grodecki at 301–443–8379.

The agenda for this meeting will be made available to the public two days prior the meeting date at the above-mentioned web address.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the COGME should contact Mr. Shane Rogers, Designated Federal Official within the Bureau of Health Professions, Health Resources and Services Administration, in one of following three ways: (1) Send a request to the following address: Shane Rogers, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857; (2)

call 301–443–5260; or (3) send an email to srogers@hrsa.gov.

Dated: May 3, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–11087 Filed 5–9–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number OIG–1301–N2]

Revised OIG's Provider Self-Disclosure Protocol

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This notice announces the issuance of the updated Provider Self-Disclosure Protocol (the SDP), originally published in the **Federal Register** on October 30, 1998 (63 FR 58399). In 1998, the Office of Inspector General published the SDP to establish a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act), 42 U.S.C. 1320a–7b(f)). The SDP provides guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider's liability under OIG's civil monetary penalty (CMP) authorities.

Since the original publication, we identified areas where additional guidance would be beneficial to the health care community and would improve the efficient resolution of SDP matters. To that end, we issued three Open Letters to Health Care Providers in 2006, 2008, and 2009. Since the last Open Letter, we continued to evaluate our SDP process. We also solicited comments about the SDP on June 18, 2012, and we received numerous helpful comments from the public. On the basis of our experience and the comments we received, we have decided to revise the SDP in its entirety at this time. This revised SDP supersedes and replaces the 1998 **Federal Register** Notice and the Open Letters.

OIG has posted the full revision of the SDP on its Web site: *http://oig.hhs.gov/compliance/self-disclosure-info/index.asp.*

FOR FURTHER INFORMATION CONTACT: Patrice S. Drew, Congressional and Regulatory Affairs, Office of Inspector General, (202) 619–1368.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2013–11050 Filed 5–9–13; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD); 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 Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this 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 for the review and discussion of grant applications. 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: National Advisory Child Health and Human Development Council.

Date: June 6, 2013.

Open: June 6, 2013, 8:00 a.m. to 12:00 p.m.

Agenda: The agenda will include: 1) a report by the Director, NICHD; 2) Report of the Director, Division of Extramural Research; 3) Review of Council Operating Procedures; and 4) Other Business of the Council.

Closed June 6, 2013, 1:00 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Yvonne T. Maddox, Ph.D., Deputy Director, *Eunice Kenney Shriver* National Institute of Child Health, and Human Development, NIH, 9000 Rockville Pike MSC 7510, Building 31, Room 2A03, Bethesda, MD 20892, (301) 496–1848.

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.nichd.nih.gov/about/advisory/nachhd/Pages/index.aspx,* where an agenda and any additional information for the meeting will be posted when available.

In order to facilitate public attendance at the open session of Council, additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions at: *http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment program, National Institutes of Health, HHS).

Dated: May 3, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11102 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; SBIR Topic 304 ''Development of Blood-based Methods for the Detection of Cancer Recurrence in Post-Therapy Breast Cancer Patients.

Date: June 4, 2013.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute West Tower, 9609 Medical Center Drive, Room 7W122, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Bethesda, MD 20892–8328, 240–276–6349, *ahmads@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; SBIR Topic 305 ''Novel Digital X-ray Sources for Cancer Imaging Applications''.

Date: June 4, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute West Tower, 9609 Medical Center Drive, 7W122, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Bethesda, MD 20892–8328, 240–276–6349, *ahmads@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 6, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11097 Filed 5–9–13; 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: June 6–7, 2013.

Time: 2:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–594–3243, *haririmf@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: May 6, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11101 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of 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: Office of Research Infrastructure Programs Special Emphasis Panel; Comparative Medicine Resources.

Date: June 5–6, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 1082, 6701 Democracy Blvd., Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sheri A. Hild, Ph.D., Scientific Review Officer, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1082, Bethesda, MD 20892–4874, 301–435–0811, *hildsa@mail.nih.gov.*

Name of Committee: Office of Research Infrastructure Programs Special Emphasis Panel; Comparative Medicine Training.

Date: June 25–26, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 1082, 6701 Democracy Blvd., Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sheri A. Hild, Ph.D., Scientific Review Officer, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1082, Bethesda, MD 20892–4874, 301–435–0811, *hildsa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 6, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11106 Filed 5–9–13; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Centers of Excellence

for Influenza Research and Surveillance (N01).

Date: June 3–5, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Susana Mendez, Ph.D., DVM, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, *mendezs@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: May 6, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11100 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (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 materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review.

Date: June 4, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

Contact Person: Minna Liang, Ph.D., Scientific Review Officer, Grants Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4226, MSC 9550, Bethesda, MD 20892–9550, 301–435–1432, *liangm@nida.nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; PA–11–197 NIH Pathway to Independence Award (K99).

Date: June 11, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eliane Lazar-Wesley, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4245, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, 301–451–4530, *el6r@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 3, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11103 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of 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 Environmental Health Sciences Special Emphasis Panel Screens for Toxicant Effects on Cell Differentiation.

Date: June 6–7, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709, (Virtual Meeting).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446, *eckertt1@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation–Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: May 6, 2013

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11105 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel; OmniBus Cancer Biology 3 SEP.

Date: June 11–12, 2013.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC/Rockville, 1750 Rockville Pike, Rockville, MD 20892.

Contact Person: Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Bethesda, MD 20892–8328, 240–276–6349, *ahmads@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Management, Epidemiology, and Health Behavior.

Date: June 26–27, 2013.

Time: 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Ellen K Schwartz, EDD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Bethesda, MD 20892–9750, 240–276–6384, *ellen.schwartz@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Review of K Applications.

Date: July 8, 2013.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove West, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Lynn M. Amende, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W112, MSC 9750, Bethesda, MD 20892–9750, 240–276–6345, *amendel@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 6, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11098 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Initial Review Group; Subcommittee F—Institutional Training and Education.

Date: June 19, 2013.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Room 7W034, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Timothy C. Meeker, Ph.D., MD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W624, Bethesda, MD 20892, 240–276–6464, *meekert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 6, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11095 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Program Project for Triglyceride Metabolism.

Date: June 4, 2013.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Melissa E Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Salt-Dependent Hypertension.

Date: June 5, 2013.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892–7924, 301–435–0287, *carolko@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Resource-Related Project for Stem Cells and Cardiomyopathy.

Date: June 6, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Melissa E Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 6, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11099 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse Notice of Closed 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract

proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Medication Ingestion Compliance (2231).

Date: May 14, 2013.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–402–6626, *gm145a@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Confirming Compliance (2232).

Date: May 14, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–402–6626, *gm145a@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Confirming Compliance with Experimental Pharmacotherapy Treatment of Drug Abuse (2227).

Date: May 14, 2013.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–402–6626, *gm145a@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 3, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11104 Filed 5–9–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3364–EM; Docket ID FEMA–2013–0001]

North Dakota; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of North Dakota (FEMA–3364–EM), dated April 26, 2013, and related determinations.

DATES: *Effective Date:* April 26, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 26, 2013, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the emergency conditions in certain areas of the State of North Dakota resulting from flooding beginning on April 22, 2013, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of North Dakota.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gary R. Stanley, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of North Dakota have been designated as adversely affected by this declared emergency:

Cass, Grand Forks, Pembina, Richland, Traill, and Walsh Counties for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–11108 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3363–EM; Docket ID FEMA–2013–0001]

Texas; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Texas (FEMA–3363–EM), dated April 19, 2013, and related determinations.

DATES: *Effective Date:* April 19, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 19, 2013, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Texas resulting from an explosion beginning on April 17, 2013, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Texas.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated area. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Kevin L. Hannes, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following area of the State of Texas has been designated as adversely affected by this declared emergency:

McLennan County for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–11110 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3362–EM; Docket ID FEMA–2013–0001]

Massachusetts; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Massachusetts (FEMA–3362–EM), dated April 17, 2013, and related determinations.

DATES: *Effective Date:* April 17, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 17, 2013, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the Commonwealth of Massachusetts resulting from explosions on April 15, 2013, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (''the Stafford Act''). Therefore, I declare that such an emergency exists in the Commonwealth of Massachusetts.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program through April 22, 2013.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the Commonwealth of Massachusetts have been designated as adversely affected by this declared emergency:

Middlesex, Norfolk, and Suffolk Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program at 75 percent federal funding.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator,

Federal Emergency Management Agency.

[FR Doc. 2013–11114 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3363–EM; Docket ID FEMA–2013–0001]

Texas; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Texas (FEMA–3363–EM), dated April 19, 2013, and related determinations.

DATES: *Effective Date:* May 1, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Texas is hereby amended to include the Individuals and Households Program under Section 408 of the Stafford Act, 42 U.S.C. 5174, in the following area determined to have been adversely affected by the event declared an emergency by the President in his declaration of April 19, 2013.

McLennan County for the Individuals and Households Program under Section 408 of the Stafford Act, 42 USC 5174 (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–11119 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4110–DR; Docket ID FEMA–2013–0001]

Massachusetts; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Massachusetts (FEMA–4110–DR), dated April 19, 2013, and related determinations.

DATES: *Effective Date:* April 19, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 19, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in the Commonwealth Massachusetts resulting from the severe winter storm, snowstorm, and flooding during the period of February 8–9, 2013, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Massachusetts.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Massachusetts have been designated as adversely affected by this major disaster:

Barnstable, Berkshire, Bristol, Dukes, Essex, Franklin, Hampden, Hampshire, Middlesex, Nantucket, Norfolk, Plymouth, Suffolk, and Worcester Counties for Public Assistance.

Berkshire, Bristol, Essex, Franklin, Hampden, Hampshire, Middlesex, Norfolk, Suffolk, and Worcester Counties for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

All counties within the Commonwealth of Massachusetts are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator,

Federal Emergency Management Agency.

[FR Doc. 2013–11111 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4111–DR; Docket ID FEMA–2013–0001]

New York; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New York (FEMA–4111–DR), dated April 23, 2013, and related determinations.

DATES: *Effective Date:* April 23, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 23, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of New York resulting from a severe winter storm and snowstorm during the period of February 8–9, 2013, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of New York.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated area and Hazard Mitigation throughout the State. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following area of the State of New York has been designated as adversely affected by this major disaster:

Suffolk County for Public Assistance.

Suffolk County for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

All counties within the State of New York are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–11116 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4112–DR; Docket ID FEMA–2013–0001]

Kansas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Kansas (FEMA–4112–DR), dated April 26, 2013, and related determinations.

DATES: *Effective Date:* April 26, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 26, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Kansas resulting from a snowstorm during the period February 20–23, 2013 is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Kansas.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide emergency protective measures and buildings and equipment (Categories B and E) under the Public Assistance program in the designated areas and Hazard Mitigation throughout the State. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Joe M. Girot, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Kansas have been designated as adversely affected by this major disaster:

Barber, Barton, Dickinson, Ellis, Franklin, Harper, Harvey, Hodgeman, Kingman, Marion, McPherson, Ness, Osage, Osborne, Pawnee, Phillips, Pratt, Rice, Rooks, Rush, Russell, Smith, and Stafford Counties for emergency protective measures and buildings and equipment (Categories B and E) under the Public Assistance program.

Barton, Dickinson, Ellis, Franklin, Harper, Harvey, Hodgeman, Kingman, Marion, McPherson, Ness, Osage, Osborne, Pawnee, Phillips, Pratt, Rice, Rooks, Rush, Russell, Smith, and Stafford Counties for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

Barber County for snow assistance under the Public Assistance program for any continuous 72-hour period during or proximate to the incident period.

All counties within the State of Kansas are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–11118 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Availability of the Final Record of Decision for the Programmatic Environmental Impact Statement for Northern Border Activities and Technical Corrections to the Final Programmatic Environmental Impact Statement for Northern Border Activities

AGENCY: U.S. Customs and Border, Protection, DHS.

ACTION: Notice of availability.

SUMMARY: U.S. Customs and Border Protection (CBP) announces the availability of the Final Record of Decision (ROD) for the Programmatic Environmental Impact Statement for Northern Border Activities (PEIS). The release of this Final ROD concludes a process of assessment of the potential for CBP activities to affect the environment along the northern border and recommends what measures CBP anticipates it will routinely consider to reduce the potential for environmental harm from its actions. CBP is also making certain technical corrections to the PEIS to ensure that it accurately describes CBP activities and the preparation of the PEIS itself. This notice describes those technical corrections.

ADDRESSES: You may obtain copies of the Final ROD and the PEIS revisions by accessing the following Internet addresses: *http://www.cbp.gov/xp/cgov/about/ec/nepa_pr/nepa_by_state/nobo_peis/* and *http://www.dhs.gov/nepa.* Alternatively you may email *cbpenvironmentalprogram@cbp.dhs.gov* before August 8, 2013 or telephone (202–325–4191) to request a copy of the Final ROD.

FOR FURTHER INFORMATION CONTACT: Jennifer DeHart Hass, CBP, Office of Administration, telephone 202–325–4191. You may also visit the project's Web page through: *http://www.cbp.gov/xp/cgov/about/ec/nepa_pr/nepa_by_state/nobo_peis/.*

SUPPLEMENTARY INFORMATION: The Northern Border PEIS was prepared to inform CBP decision-makers about potential environmental impacts resulting from CBP Northern Border activities. The action alternatives considered in the PEIS represent reasonably foreseeable changes to CBP's Northern Border security program that could potentially occur over the next five to seven years.

On July 27, 2012, CBP published a Notice of Availability (NOA) in the **Federal Register** (77 FR 44259) announcing the availability of the Final PEIS and availability of the Draft ROD for the Northern Border PEIS for a 30-day public review prior to making a decision on what alternative CBP would select from among those analyzed. Previous **Federal Register** notices published for the PEIS are as follows:

- Notice of Intent (NOI) to prepare four PEISs, July 6, 2010, 75 FR 38822.
- NOI to Prepare One PEIS, November 9, 2010, 75 FR 68810.
- NOA of a Draft PEIS, September 16, 2011, 76 FR 57751.

The Executive Director for Facilities Management signed the Final ROD on April 11, 2013. It is available on the CBP Web site at *http://www.cbp.gov/xp/cgov/about/ec/nepa_pr/nepa_by_state/nobo_peis/*. The Final ROD confirms CBP's determination that the Detection, Inspection, Surveillance, and Communications Technology Expansion Alternative is most representative of the approach CBP will employ in order to enhance response to emergent border security threats while advancing trade and travel facilitation over the next five to seven years. The Detection, Inspection, Surveillance, and Communications Technology Expansion Alternative would focus on increased patrol activity and deploying more and better technologies to support CBP's detection, inspection, and surveillance capabilities and operational communications. This alternative is consistent with current statements of national policy with regard to Northern Border security and trade and travel facilitation goals.

The release of this Final ROD concludes a process of assessment of the potential for CBP activities to impact the environment along the northern border and recommends what measures CBP anticipates it will routinely consider to reduce the potential for environmental harm from its actions. Other alternatives studied in the PEIS included the Facilities Development and Improvement Alternative, the Tactical Security Infrastructure Deployment Alternative, and the Flexible Direction Alternative. The Flexible Direction Alternative would allow CBP to employ any of the tools and activities in the other alternatives. CBP determined that although the Flexible Direction Alternative fully meets the purpose and need presented in the PEIS, its approach is more resource intensive than the risk-based approach envisioned for enhancing border security. If within five years of signing this ROD, CBP is required to adopt additional measures beyond the scope of the alternative selected at this time, CBP will evaluate whether it should issue a ROD adopting the Flexible Direction Alternative.

Comment Response and Clarifications Incorporated Into the Final ROD

In response to a comment received on the Draft ROD and further consideration of its decision, CBP included certain clarifications in the Final ROD.

Easement Clarification

During the 30-day period following the public release of the Final PEIS and Draft ROD, CBP received seven inquiries and only one comment on the Final PEIS. This comment was from the U.S. Department of Agriculture's (USDA) Natural Resources Conservation Service (NRCS). Along with providing information on all NRCS easements along the Northern Border, NRCS requested that CBP attempt to avoid constructing facilities and infrastructure within NRCS conservation easements. CBP addressed this comment in the Final ROD by including easements in the list of Federal lands for which CBP should use the Borderlands Management Task Force structure to enhance coordination among land-managers regarding usage for CBP construction, modification, and maintenance projects.

Best Management Practices (BMPs) Clarifications

BMP A.1, described in the Final ROD, is focused on improving CBP coordination with the Department of Interior (DOI) and USDA during project planning. The Final ROD clarifies this BMP's applicability to DOI managed lands and lands held in trust for American Indians and Federally-recognized Indian tribes. The Final ROD further emphasizes that CBP will also coordinate and consult with governments of tribes or nations when activities impact such lands held in trust. In response to NRCS comments, CBP also included applicable easements to the list of USDA managed land.

BMP A.5 is concerned with minimizing impacts to migratory birds and threatened and endangered flying species from CBP towers. The Final ROD clarifies that the BMP applies to construction of new antennae structures. Furthermore, when CBP is

collocating equipment on antennae structures owned by non-Federal entities, it can only implement BMPs for the structure in accordance with the owner's willingness, structural capability, and zoning restrictions.

Additional Clarifications

In section V, ''Implementation,'' CBP made minor wording changes to further clarify that the selected alternative describes the lines of activity that CBP believes it would take in response to future changes in the threat environment and security priorities.

Also, in section II, ''Factors Considered in the Decision,'' the ROD now reiterates the theme that partnerships and intelligence are a vital part of resolving emerging cross-border threats prior to them reaching the border.

Technical Corrections to the PEIS

During its deliberations, CBP found that certain technical corrections to the Final PEIS were needed. These technical corrections to the PEIS ensure that the PEIS accurately describes CBP activities and the preparation of the PEIS itself. The technical corrections are confined to: (1) The description of certain technologies used for inspecting vehicles and cargo, and (2) the list of government personnel involved in the preparation of the Final PEIS and Final ROD.

The technical corrections CBP is making to the Final PEIS do not change any impact determinations in the PEIS. Accordingly, CBP will not reissue the PEIS for public input. CBP has incorporated the technical corrections, as they are described below, into the online version of the PEIS.

Gamma imaging and X-ray Inspection Technologies

On page 2–11 and in the table on page 2–12 of the Final PEIS, the discussion of inspection technologies included in the Detection, Inspection, Surveillance, and Communications Technology Expansion Alternative was amended to better describe CBP's use of gamma imaging inspection systems and X-ray technologies.

The bullet at the bottom of page 2–11 explains why CBP evaluates the usefulness of commercial off the shelf technologies. In order to reflect the proper application of X-ray scanners by CBP, the bullet at the bottom of page 2–11 was amended so it now reads as follows: ''Performing inspections using more personal radiation detectors (PRD), RIIDs and NII tools such as gamma imaging inspection systems, and low and high energy x-ray inspection systems (see box on page 2–12). (CBP completed Programmatic Environmental Assessments (EA) on the deployment of various types of NII technology in 2010 and recently published a programmatic EA for the use of low energy x-ray inspection systems to scan personally owned vehicles (POVs) with the driver/passenger in the vehicle.).'' [1]

Page 2–12 of the PEIS discusses gamma imaging inspection systems and uses Vehicle and Cargo Inspection System® (VACIS) as the operative example. ''Gamma imaging inspection system'' is the general description of the impacting technology. VACIS® is merely the proprietary name for a particular brand of gamma imaging inspection system. Therefore, the PEIS should have used the more general term ''gamma imaging inspection system'' throughout the discussion. Accordingly, the relevant passage on page 2–12 was amended so it now reads: ''Gamma Imaging Inspection Systems—The gamma imaging inspection system is used to scan cargo. It can be delivered as a portal or on tracks for POEs, or mounted on a truck to be used at multiple, temporary, and/or remote locations as well as POEs. The truck-mounted system can be especially useful for those situations where the container itself is fixed.'' [2]

The discussion of X-Ray inspection technologies on page 2–12 of the PEIS incorrectly asserted that high energy X-Ray inspections systems (HEXRIS) were used by CBP to perform body scans. Neither high energy nor low-energy X-ray systems are used for body scan imaging. LEXRIS are used to scan personally owned vehicles at ports of entry while the drivers or passengers remain in their vehicles. Therefore, the discussion of HEXRIS was revised to state: ''X-Ray Imaging Systems—High Energy X-Ray Inspection Systems (HEXRIS) is a non-intrusive inspection technology for use to aid in inspecting high-density cargo containers. Low Energy X-Ray Systems are utilized to scan personally owned vehicles (POVs).'' [3]

Also, on page 8–197, in the paragraph beginning. ''Use NII Technology,'' the phrase ''high-energy X-ray imaging systems'' should be ''high-energy inspection systems.''

List of Preparers

A number of government personnel who contributed to the preparation of the Final PEIS were inadvertently omitted from the Chapter 11 List of Preparers in the Final Programmatic Environmental Impact Statement. This notice amends the Final PEIS Preparers table to add the following personnel according to their name and description of their associated professional experience:

- Paula Bienenfeld (Parsons), Ph.D., Anthropology—32 years: archeology; NHPA Section 106 consultation, NEPA document preparation, analysis, and review;
- Jennifer Hass (CBP), M.S. Environmental Law; J.D.—6 years: environmental planning, environmental program management, environmental issue advocacy, NEPA document preparation, analysis, and review;
- John Petrilla (CBP), B.S. Environmental Economics and Policy, M.P.P. Policy Studies—5 years: environmental planning and compliance; NEPA document preparation, analysis, and review; and
- Joseph Zidron (CBP), Masters of Public Administration—5 years: environmental planning and compliance; NEPA document preparation, analysis, and review.

Dated: May 6, 2013.

Karl H. Calvo,

Executive Director, Facilities Management and Engineering, Office of Administration.

[FR Doc. 2013–11115 Filed 5–9–13; 8:45 am]

BILLING CODE 9111–14–P

[1] This passage previously stated: ''Processing visitors and cargo more rapidly while maintaining strict security by using more and improved personal radiation detectors (PRD), RIDs, and NII tools, such as high-energy container scanners and full-body scanners (see box). (CBP completed a programmatic Environmental Assessment (EA) on the deployment of various types of NII technology in 2009 and recently published EAs for the use of high-energy scanners for both cargo and people.)''

[2] This passage previously stated: ''Vehicle and Cargo Inspection System—This is a gamma-ray backscatter imaging system used for inspecting cargoes. It can be delivered as a portal for POEs or mounted on a truck to be used at multiple, temporary, and/or remote locations. The truck-mounted system can be especially useful for those situations where the container itself is fixed, such as a railroad car.''

[3] This passage previously stated: ''High-Energy X-Ray Imaging Scanners—High-energy imaging scanners scan a passenger by rastering or moving a single high-energy X-ray beam rapidly over the body. The signal strength of detected backscattered X-rays from a known position then allows a highly realistic image to be reconstructed (EPIC, 2010).''

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–19]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Office of Enterprise Support Programs, Program Support Center, HHS, room 12–07, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Agriculture:* Ms. Brenda Carignan, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 337, Washington, DC 20024, (202) 401–0787; *Coast Guard:* Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2100 Second St. SW., Stop 7901, Washington, DC 20593–0001; (202) 475–5609; *NASA:* Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; (This is not toll-free numbers).

Dated: May 2, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 05/10/2013

Suitable/Available Properties

Building

California

Laufman Wildlife Office
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320003
Status: Unutilized
Comments: Off-site removal; 1,285 sf.; office; 60 months vacant; very poor conditions; repairs a must; rodents w/Hanta virus presence

Water Treatment Building
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320005
Status: Excess
Comments: Off-site removal; 216 sf.; utility water treatment; 240 months vacant; very poor conditions; major repairs needed; Hanta virus presence

Laufman Paper Storage
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320006
Status: Unutilized
Comments: Off-site removal; 85 sf.; storage; 240 months vacant; very poor conditions; rodents w/Hanta virus

Office
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320008
Status: Unutilized
Comments: Off-site removal; 2,057 sf.; office; 36 months vacant; very poor conditions; repairs a must; rodents w/Hanta virus presence

Laufman Engine Bay Warehouse
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320009
Status: Unutilized
Comments: Off-site removal; 2,801 sf.; storage; 60 months vacant; very poor conditions; repairs a must; rodents w/Hanta virus

Laufman Flammable Storage
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320010
Status: Excess
Comments: Off-site removal; 36 months vacant; fire station; very poor conditions; major repairs needed; rodents w/Hanta virus presence

Laufman Barracks
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture

Property Number: 15201320011
Status: Unutilized
Comments: Off-site removal; 2,112 sf.; barracks; 60 months vacant; very poor conditions; need major repairs; rodents w/ Hanta virus presence

Laufman Warehouse
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320012
Status: Unutilized
Comments: Off-site removal; 1,836 sf.; storage; 60 months vacant; lead-based paint; very poor conditions; unidentified chemical spills; rodents w/Hanta virus presence

Laufman Fuelwood Storage
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320013
Status: Unutilized
Comments: Off-site removal; 176 sf.; storage; dilapidated; 60 months vacant; major repairs needed; rodents w/Hanta virus presence

Laupman Timber Office
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320014
Status: Excess
Comments: Off-site removal; 1,028 sf.; office; 60 months vacant; deteriorated; no roof; repairs a must; rodents w/Hanta virus presence

Shed
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320015
Status: Unutilized
Comments: Off-site removal; 80 sf.; shed; 120 months vacant; very poor conditions; rodents w/Hanta virus presence

Laufman Fire Office
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320016
Status: Unutilized
Comments: Off-site removal; 700 sf.; storage; 60 months vacant; very poor conditions; lead-based paint; repairs a must; rodents w/Hanta virus presence

Laufman Silvilcultupe
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320017
Status: Excess
Comments: Off-site removal; 1,478 sf.; 60 months vacant; very poor conditions; repairs a must; rodents w/Hanta virus presence

Laufman Upper Pumphouse
446525 Milford Grade Rd.
Milford CA 96121
Landholding Agency: Agriculture
Property Number: 15201320019
Status: Unutilized
Comments: Off-site removal; 96 sf.; utility; 60 months vacant; very poor conditions; rodents w/Hanta virus presence

Unsuitable Properties

Building

Ohio

2 Buildings
Glenn Research Center
Rye Beach Island OH 44839
Landholding Agency: NASA
Property Number: 71201320001
Status: Unutilized
Directions: Facilities 8132 and 8170
Comments: w/in secured area; public access denied & no alternative method to gain access without compromising nat'l security
Reasons: Secured Area

Tennessee

U.S. Coast Guard Paris Landing
700 Coast Guard Rd.
Buchanan TN 38222
Landholding Agency: Coast Guard
Property Number: 88201320003
Status: Excess
Comments: Public access denied & no alternative method to gain access w/out compromising nat'l security
Reasons: Secured Area

[FR Doc. 2013–10865 Filed 5–9–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[13XE1700DX EEEE600000 EX1SF0000.DSA000]

Final Safety Culture Policy Statement

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE), Interior.

ACTION: Notice.

SUMMARY: The Bureau of Safety and Environmental Enforcement (BSEE) issues this Final Statement of Policy to announce its expectation that individuals and organizations performing or overseeing activities regulated by BSEE establish and maintain a positive safety culture commensurate with the significance of their activities and the nature and complexity of their organizations and functions. The BSEE defines safety culture as the core values and behaviors of all members of an organization that reflect a commitment to conducting business in a safe and environmentally responsible manner. Further, it is important for all lessees, the owners or holders of operating rights, designated operators or agents of the lessee(s), pipeline right-of-way holders, State lessees granted a right-of-use and easement, and contractors to foster in personnel an appreciation for the importance of safety and environmental stewardship, emphasizing the need for their integration into performance objectives to achieve optimal protection and production.

FOR FURTHER INFORMATION CONTACT: Mr. Keith Petka, Safety and Environmental Management Systems Branch at (703) 787–1736, or by email at *SEMS@bsee.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 20, 2012, BSEE published a Notice in the **Federal Register** requesting comments on its Draft Statement of Policy announcing the expectation that individuals and organizations performing or overseeing activities regulated by BSEE establish and maintain a positive safety culture commensurate with the significance of their activities and the nature and complexity of their organizations and functions [77 FR 75443]. The comment period for this notice closed on March 20, 2013.

II. Summary of Comments on Draft Safety Culture Policy Statement

In response to the **Federal Register** notice, BSEE received 32 sets of comments from oil and gas companies (operators and contractors), industry associations, environmental organizations, and individuals. In the following section, we address the general comments by topic and discuss any changes made to the Policy Statement based on these comments. Comments that are not related to the notice or that are outside the scope of the policy statement are not addressed. All of the comments BSEE received are posted on *www.regulations.gov,* under docket number BSEE–2012–0017.

Comments by Topic

Support for BSEE's Issuance of Draft Safety Culture Policy Statement

A majority of commenters approved of BSEE's publication of the draft safety culture policy statement and identified it as an important starting point to initiate substantial discussions focused on improving the safety culture on the Outer Continental Shelf (OCS).

Nine Safety Culture Characteristics

The majority of commenters expressed agreement with the nine characteristics of safety culture that BSEE listed in the policy statement. Some commenters recommended modifications to the safety culture characteristics, such as the need for equipment control and integrity. In response to these comments, BSEE has altered the title of characteristic two from ''Problem Identification and

Resolution'' to ''Hazard Identification and Risk Management'' and acknowledged equipment control in characteristic four. The BSEE feels that these changes better align with the common vocabulary used on the OCS for identifying potential safety issues as well as concentrating on the inherent risk in oil and gas activities. A positive safety culture would focus on continuously appraising hazards during the various exploration and production activities while adequately directing resources to the highest risks in order to best enhance safety.

Other commenters suggested adding new characteristics such as implementation, measurement and evaluation, and reward and recognition. The BSEE believes these are valuable ideas, but are too specific for inclusion in this policy statement. It is not BSEE's intention to mandate safety culture requirements. The ultimate goal for releasing this policy statement is to outline the critical traits that are present in a positive safety culture while initiating a constructive dialogue on how regulators, industries, and the public can collaborate on improving the overall safety on the OCS. However, we will consider utilizing these concepts as we plan future strategies outside of this policy statement.

Safety Versus Production

Many commenters noted that the policy statement appears to subordinate safety to production. Most of the commenters who commented on this issue pointed out that safety and production are often viewed as being in competition with each other. All of those who commented on this issue emphasized the need to clarify that safety should not be secondary to production.

The BSEE agrees with these comments and has altered the policy statement to read, ''Each and every person involved in the wide range of activities associated with the offshore oil and gas program should emphasize the need to integrate safety and environmental stewardship into personal, company, and government performance objectives.''

Prescription of Safety Culture

Many commenters requested that BSEE refrain from mandating the adoption of a safety culture and that the policy statement not be too prescriptive. The commenters cited the need for flexibility in the adoption of safety culture and expressed the concern that the very act of mandating or prescribing safety culture activities would counteract the cultural assimilation that the safety culture statement intends to advance. It is not BSEE's intention to mandate safety culture requirements. The BSEE believes this would be counterproductive to building a positive safety culture; therefore, we are not prescribing a safety culture policy.

Differences Between Occupational and Process Safety

Many commenters stated that the policy statement should acknowledge a difference between occupational and process safety. Some commenters noted that the measures taken to advance occupational and process safety each are different: Occupational safety focuses primarily on behaviors while process safety focuses on management framework and better involves organization leaders. One commenter stated that occupational safety efforts concentrate on individual worker actions while process safety efforts concentrate on preventing high consequence, low likelihood events through engineering design.

A number of commenters expressed concern that the broad direction to adopt a safety culture is often translated into pressure on workers to avoid injuries. According to the commenters, this would occur without a concomitant requirement for a safety culture commitment throughout all levels of the organization.

The BSEE agrees with the comments that there is a difference between process safety and occupational safety. In an effort to involve all types of safety and all organization personnel, the definition of safety culture and several parts of the statement have been edited to better encompass all roles in an organization, and characteristic three has therefore been edited to read, ''All individuals take personal responsibility for process and personal safety as well as environmental stewardship.''

Lack of Environmental Awareness

Several commenters stated that the policy statement does not adequately present the need for OCS organizations to focus on both safety and environmental issues. One commenter described the link between environmental safety and process safety that is vital to the OCS safety culture. Another commenter indicated that the statement ''must clearly and consistently emphasize the importance of environmental health and safety in addition to human safety.''

The BSEE agrees that environmental protection plays a significant role in the activities on the OCS and we have edited the policy statement to reflect this importance.

Learn From Others

A number of commenters stated that other organizations and Federal agencies have already led safety culture transformations and encouraged BSEE to study their experiences. The BSEE appreciates this suggestion and is currently working to develop information sessions and workshops with various organizations that have had extensive experience with safety culture in comparable industries (*e.g.,* Federal Aviation Administration, Nuclear Regulatory Commission, Petroleum Safety Authority Norway, etc.).

Stop Work Authority

Many commenters encouraged the use of the stop work authority. They emphasized that stop work authority could be used as a tool for workers to use in preventing accidents and as a safety cultural assimilation method. Several of those commenters who advocated special mention of stop work authority within the policy statement noted that while it deserves emphasis, it also needs to be carefully described in order to prevent misuse. According to the commenters, if the stop work authority were improperly applied or guided, it could exacerbate already deteriorating conditions.

On April 5, 2013, the final rule ''Revisions to Safety and Environmental Management Systems'' was published in the **Federal Register** [78 FR 20423]. This rule mandates that all operators implement stop work authority on all OCS activities regulated by BSEE. Therefore, BSEE is not making any changes to the policy statement with regard to stop work authority.

Further Involvement

Many commenters noted that BSEE should continue the dialogue on the topic of a safety culture policy statement. The majority of these comments contained recommendations that BSEE provide further details about safety culture in a future guidance document. Other commenters stated that BSEE should engage in an ongoing dialogue with stakeholders to discuss safety culture so that continued progress could be made.

Through public comments and industry input, BSEE has identified several tools that can effectively encourage a positive safety culture on the OCS. These include:

1. Forums and workshops with industry and other agencies to discuss safety culture initiatives;

2. Establishing a research program that can identify safety areas in need of improvement; or

3. Writing guidance documents that describe best practices and case studies for safety culture advancement.

The BSEE is currently exploring these options and will look towards further collaboration with industry and the public.

III. Statement of Policy

The BSEE defines safety culture as the core values and behaviors of all members of an organization that reflect a commitment to conduct business in a manner that protects people and the environment.

It is necessary for everyone participating in the exploration, development, and production of offshore oil and gas—from a contract service provider, to the leaseholder, to the government regulator—to realize the importance of a culture that promotes safety and environmental stewardship to a vigorous and respected offshore energy industry. Each and every person involved in the wide range of activities associated with the offshore oil and gas program should emphasize the need to integrate safety and environmental stewardship into personal, company, and government performance objectives. Continued improvement in safety and environmental protection will demonstrate to the American public that access to the valuable offshore energy resources can be accomplished while respecting the environment and protecting the offshore workers.

Experience has shown that certain personal and organizational characteristics are present in a culture that promotes safety and environmental responsibility. A characteristic, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in situations that may have conflicting goals (*e.g.,* production, schedule, and the cost of the effort versus safety and environmental protection).

The following are some of the characteristics that typify a robust safety culture:

1. *Leadership Commitment to Safety Values and Actions.* Leaders demonstrate a commitment to safety and environmental stewardship in their decisions and behaviors;

2. *Hazard Identification and Risk Management.* Issues potentially impacting safety and environmental stewardship are promptly identified, fully evaluated, and promptly addressed or corrected commensurate with their significance;

3. *Personal Accountability.* All individuals take personal responsibility for process and personal safety, as well as environmental stewardship;

4. *Work Processes.* The process of planning and controlling work activities is implemented so that safety and environmental stewardship are maintained while ensuring the correct equipment for the correct work;

5. *Continuous Improvement.* Opportunities to learn about ways to ensure safety and environmental stewardship are sought out and implemented;

6. *Environment for Raising Concerns.* A work environment is maintained where personnel feel free to raise safety and environmental concerns without fear of retaliation, intimidation, harassment, or discrimination;

7. *Effective Safety and Environmental Communication.* Communications maintain a focus on safety and environmental stewardship;

8. *Respectful Work Environment.* Trust and respect permeate the Organization with a focus on teamwork and collaboration; and

9. *Inquiring Attitude.* Individuals avoid complacency and continuously consider and review existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

Although there are additional traits that amplify or extend these basic characteristics, these nine characteristics are foundational to the development of an effective and functioning safety culture that recognizes the need to protect people and the environment first and foremost.

Dated: May 2, 2013.

James A. Watson,

Director, Bureau of Safety and Environmental Enforcement.

[FR Doc. 2013–11117 Filed 5–9–13; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2013–N106; FXES1112040000–134–FF04EF2000]

Endangered and Threatened Wildlife and Plants; Receipt of Application for Incidental Take Permit; Availability of Proposed Low-Effect Habitat Conservation Plan and Associated Documents; Polk County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment/information.

SUMMARY: We, the Fish and Wildlife Service (Service), announce the availability of an incidental take permit (ITP) application and a Habitat Conservation Plan (HCP). Vulcan Materials Company, Florida Rock Divisions (dba Florida Rock Industries, Inc. a subsidiary of Vulcan Materials Company) (applicant), requests an ITP under the Endangered Species Act of 1973, as amended (Act). The applicant's HCP describes the minimization and mitigation measures proposed to address the effects of the project on the sand skink and gopher tortoise. We invite written comments on the ITP application and HCP.

DATES: Written comments on the ITP application and HCP should be sent to the South Florida Ecological Services Office (see **ADDRESSES**) and should be received on or before June 10, 2013.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section below for information on how to submit your comments on the ITP application and HCP. You may obtain a copy of the ITP application and HCP by writing the South Florida Ecological Services Office, Attn: Permit number TE01724B–0, U.S. Fish and Wildlife Service, 1339 20th Street, Vero Beach, FL 32960–3559. In addition, we will make the ITP application and HCP available for public inspection by appointment during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Brian Powell, Wildlife Biologist, South Florida Ecological Services Office, Vero Beach, Florida (see **ADDRESSES**); telephone: 772–562–3909, extension 315.

SUPPLEMENTARY INFORMATION: We announce the availability of an ITP application and HCP. Vulcan Materials Company, Florida Rock Divisions (dba Florida Rock Industries, Inc., a subsidiary of Vulcan Materials Company) (applicant), requests an ITP under the Act. The applicant proposes incremental mining of sand reserves throughout the permitted mining limits of the approximately 488.35-acre project area over the life of the mine.

The site has been divided into five phases, based on the anticipated progression of the mining operation. Within Phase I, the applicant anticipates taking about 6.72 acres of breeding, feeding, and sheltering habitat for the sand skink (*Neopseps reynoldsi*), bluetail mole skink (*Eumeces egregius lividus*), and gopher tortoise (*Gopherus polyphemus*), incidental to land preparation for the expansion of existing sand mining operations located in Polk County, Florida (project). The extent of direct impacts in future phases is currently undetermined; however, based on the current USFWS guidelines, within Phases II, III, and IV,

approximately 201.17 acres of the site appear to be suitable for the gopher tortoise, and approximately 130.75 acres appear to be suitable for the two skink species. The applicant's HCP describes the minimization and mitigation measures proposed to address the effects of the project on the sand skinks and gopher tortoise.

Applicant's Proposed Project

We received an application from the applicant for an incidental take permit, along with a proposed habitat conservation plan (HCP). The applicant requests a 20-year permit under section 10(a)(1)(B) of the Act (87 Stat.884; 16 U.S.C. 1531 *et seq.*). The applicant proposes incremental mining of sand reserves throughout the permitted mining limits of the approximately 488.35-acre project area over the life of the mine. The site has been divided into five phases, based on the anticipated progression of the mining operation. Within Phase I, the applicant anticipates taking about 6.72 acres of breeding, feeding, and sheltering habitat for the sand skink (*Neopseps reynoldsi*), bluetail mole skink (*Eumeces egregius lividus*), and gopher tortoise (*Gopherus polyphemus*), incidental to land preparation for the expansion of existing sand mining operations located in Polk County, Florida (project).

The extent of direct impacts in future phases is currently undetermined; however, based on the current USFWS guidelines, within Phases II, III, and IV, approximately 201.17 acres of the site appear to be suitable for the gopher tortoise, and approximately 130.75 acres appear to be suitable for the two skink species. The applicant's HCP describes the minimization and mitigation measures proposed to address the effects of the project on the sand skinks and gopher tortoise. In advance of the progression of the mining operations into future phases, quantitative surveys will be conducted for the skinks and gopher tortoises to determine the occupancy and extent of occupancy within these suitable areas. The completion of these surveys will be subject to the guidelines at the time the surveys are conducted. Construction activities associated with the Diamond Sand Mine will take place within Sections 3 and 4, Township 30 South, Range 28 East, Polk County, Florida.

The applicant proposes to mitigate for impacts to occupied skink habitat within Phase I by purchasing approximately 13.44 mitigation bank credits at the Tiger Creek Conservation Bank in Polk County, Florida, a bank within the service area of skinks. Direct impacts to occupied skink habitat within the future phases will be mitigated at the same ratio, utilizing the same mitigation bank. Additionally, the applicant proposes to mitigate for impacts to occupied gopher tortoise habitat within Phase I, as well as in future phases, by relocating gopher tortoises and any recovered eggs to a recipient site approved by the Florida Fish and Wildlife Conservation Commission.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including the mitigation measures, will individually and cumulatively have a minor or negligible effect on the species covered in the HCP. Therefore, issuance of the ITP is a ''low-effect'' action and qualifies as a categorical exclusion under the National Environmental Policy Act (NEPA) (40 CFR 1506.6), as provided by the Department of the Interior Manual (516 DM 2 Appendix 1 and 516 DM 6 Appendix 1). We base our determination that issuance of the ITP qualifies as a low-effect action on the following three criteria: (1) Implementation of the project would result in minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) Implementation of the project would result in minor or negligible effects on other environmental values or resources; and (3) Impacts of the project, considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result, over time, in cumulative effects to environmental values or resources that would be considered significant. As more fully explained in our environmental action statement and associated Low Effect Screening Form, the applicants' proposed project qualifies as a ''low-effect'' project. This preliminary determination may be revised based on our review of public comments that we receive in response to this notice.

Public Comment

If you wish to comment on the ITP application and HCP, you may submit comments by any one of the following methods:

Email: Brian_Powell@fws.gov. Use ''Attn: Permit number TE01724B–0'' as your message subject line.

Fax: Brian Powell, (772) 562–4288, Attn.: Permit number TE01724B–0.

U.S. mail: Brian Powell, Wildlife Biologist, South Florida Ecological Services Field Office, Attn: Permit number TE01724B–0, U.S. Fish and Wildlife Service, 1339 20th Street, Vero Beach, FL 32960–3559.

In-person drop-off: You may drop off information during regular business hours at the above office address.

Before including your address, phone number, email address, or other personal identifying information in your comments, 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.

Next Steps

The Service will evaluate the HCP and comments submitted thereon to determine whether the applications meet the requirements of section 10(a) of the Act. The Service will also evaluate whether issuance of the section 10(a)(1)(B) ITP complies with section 7 of the Act by conducting an intra-Service section 7 consultation. The results of this consultation, in combination with the above findings, will be used in the final analysis to determine whether or not to issue the ITP. If it is determined that the requirements of the Act are met, the ITP will be issued.

Authority

We provide this notice under Section 10 of the Endangered Species Act (16 U.S.C. 1531 et seq.) and NEPA regulations (40 CFR 1506.6).

Dated: May 6, 2013.

Larry Williams,

Field Supervisor, South Florida Ecological Services Office.

[FR Doc. 2013–11163 Filed 5–9–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

MMAA104000

Environmental Documents Prepared for Oil, Gas, and Mineral Operations by the Gulf of Mexico Outer Continental Shelf (OCS) Region

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of the Availability of Environmental Documents Prepared for OCS Mineral Proposals by the Gulf of Mexico OCS Region.

SUMMARY: BOEM, in accordance with Federal Regulations that implement the National Environmental Policy Act

(NEPA), announces the availability of NEPA-related Site-Specific Environmental Assessments (SEAs) and Findings of No Significant Impact (FONSIs). These documents were prepared during the period January 1, 2013, through March 31, 2013, for oil, gas, and mineral-related activities that were proposed in the Gulf of Mexico, and are more specifically described in the Supplementary Information Section of this notice.

FOR FURTHER INFORMATION CONTACT: Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, Attention: Public Information Office (GM 250E), 1201 Elmwood Park Boulevard, Room 250, New Orleans, Louisiana 70123–2394, or by calling 1–800–200–GULF.

SUPPLEMENTARY INFORMATION: BOEM prepares SEAs and FONSIs for certain proposals that relate to exploration, development, production, and transport of oil, gas, and mineral resources on the Federal OCS. These SEAs examine the potential environmental effects of proposed activities and present BOEM conclusions regarding the significance of those effects. The SEAs are used as a basis for determining whether or not approval of the proposals constitutes a major Federal action that significantly affects the quality of the human environment in accordance with NEPA Section 102(2)(C). A FONSI is prepared in those instances where BOEM finds that approval will not result in significant effects on the quality of the human environment. The FONSI briefly presents the basis for that finding and includes a summary or copy of the SEA. This notice constitutes the public notice of availability of environmental documents required under the NEPA Regulations.

Activity/operator	Location	Date
Apache Corporation, Structure Removal, SEA ES/SR 13–006	East Cameron, Block 48, Lease OCS–G 00768, located 18 miles from the nearest Louisiana shoreline.	1/7/2013
Tana Exploration Company LLC, Structure Removal, SEA ES/SR 13–008.	Eugene Island, Block 98, Lease OCS–G 26023, located 20 miles from the nearest Louisiana shoreline.	1/7/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–310	High Island, Block 176, Lease OCS–G 23588, located 23 miles from the nearest Louisiana shoreline.	1/8/2013
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 12–302.	High Island, Block 47, Lease OCS–G 23193, located 16 miles from the nearest Texas shoreline.	1/8/2013
Noble Energy, Inc., Exploration Plan, SEA R–5764	Mississippi Canyon, Block 948, Lease OCS–G 28030, located 62 miles from the nearest Louisiana shoreline.	1/8/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–306	Mobile, Block 830, Lease OCS–G 27973, located 5 miles from the nearest Alabama shoreline.	1/8/2013
Black Elk Energy Offshore Operations, LLC, Structure Removal, SEA ES/SR 13–001.	East Cameron, Block 160, Lease OCS–G 00541, located 44 miles from the nearest Louisiana shoreline.	1/9/2013
Black Elk Energy Offshore Operations, LLC, Structure Removal, SEA ES/SR 13–002.	East Cameron, Block 160, Lease OCS–G 00541, located 45 miles from the nearest Louisiana shoreline.	1/9/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 12–324 ..	High Island, Block A515, Lease OCS–G 24415, located 86 miles from the nearest Louisiana shoreline.	1/9/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–311	Main Pass, Block 104, Lease OCS–G 13960, located 9 miles from the nearest Louisiana shoreline.	1/9/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–315	Main Pass, Block 7, Lease OCS–G 21700, located 5 miles from the nearest Louisiana shoreline.	1/9/2013
Pisces Energy LLC, Structure Removal, SEA ES/SR 12–317 ..	Mustang Island, Block 740, Lease OCS–G 05980, located 230 miles from the nearest Texas shoreline.	1/9/2013
Black Elk Energy Offshore Operations, LLC, Structure Removal, SEA ES/SR 13–003.	West Cameron, Block 20, Lease OCS–G 00680, located 4 miles from the nearest Louisiana shoreline.	1/9/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–307 & 12–308.	Eugene Island, Block 106, Lease OCS–G 17966, located 20 miles from the nearest Louisiana shoreline.	1/10/2013
Dynamic Offshore Resources, LLC, Structure Removal, SEA ES/SR 12–327.	Galveston, Block 223, Lease OCS–G 03738, located 15 miles from the nearest Texas shoreline.	1/10/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 12–320 ..	South Timbalier, Block 217, Lease OCS–G 13937, located 44 miles from the nearest Louisiana shoreline.	1/10/2013
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 13–009.	Vermilion, Block 102, Lease OCS–G 03393, located 28 miles from the nearest Louisiana shoreline.	1/10/2013
Anglo-Suisse Offshore Partners, LLC, Structure Removal, SEA ES/SR 06–116.	West Delta, Block 117, Lease OCS–G 01101, located 23 miles from the nearest Louisiana shoreline.	1/10/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 12–321 ..	Eugene Island, Block 163, Lease OCS–G 17977, located 30 miles from the nearest Louisiana shoreline.	1/14/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 12–323 ..	Eugene Island, Block 318, Lease OCS–G 27121, located 63 miles from the nearest Louisiana shoreline.	1/14/2013
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 12–283.	South Timbalier, Block 77, Lease OCS–G 04827, located 19 miles from the nearest Louisiana shoreline.	1/14/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–312 & 12–313.	East Cameron, Block 47, Lease OCS–G 00767, located 17 miles from the nearest Louisiana shoreline.	1/15/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–314	Eugene Island, Block 108, Lease OCS–G 03811, located 23 miles from the nearest Louisiana shoreline.	1/15/2013
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 13–010.	High Island, Block 47, Lease OCS–G 23193, located 14 miles from the nearest Texas shoreline.	1/15/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–309	Main Pass, Block 7, Lease OCS–G 21700, located 4 miles from the nearest Louisiana shoreline.	1/15/2013
LLOG Exploration Offshore, L.L.C., Exploration Plan, SEA R–5774.	Mississippi Canyon, Block 253, Lease OCS–G 24062, located 54 miles from the nearest Louisiana shoreline.	1/15/2013
WesternGeco, LLC, Geological & Geophysical Survey, SEA L12–032.	Walker Ridge, Keathley Canyon, Amery Terrace & Sigsbee Escarpment, located greater than 160 miles from the nearest shoreline.	1/15/2013

Activity/operator	Location	Date
Apache Corporation, Structure Removal, SEA ES/SR 12–303, 12–304, & 12–305.	West Cameron, Block 28, Lease OCS–G 16104, located 4 miles from the nearest Louisiana shoreline.	1/15/2013
Dynamic Offshore Resources, LLC, Structure Removal, SEA ES/SR 12–326.	West Cameron, Block 432, Lease OCS–G 23771, located 65 miles from the nearest Louisiana shoreline.	1/15/2013
Shell Offshore Inc., Exploration Plan, SEA R–5737	Alaminos Canyon, Block 857, Lease OCS–G 17565, located 134 miles from the nearest Louisiana shoreline.	1/17/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 12–319 ..	West Delta, Block 42, Lease OCS–G 16470, located 12 miles from the nearest Louisiana shoreline.	1/17/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–007	Main Pass, Block 104, Lease OCS–G 13960, located 9 miles from the nearest Louisiana shoreline.	1/18/2013
Black Elk Energy Offshore Operations, LLC, Structure Removal, SEA ES/SR 12–328.	South Marsh Island, Block 23, Lease OCS–G 00778, located 41 miles from the nearest Louisiana shoreline.	1/18/2013
WesternGeco, LLC, Geological & Geophysical Survey, SEA L12–036.	Located in the Central Planning Area of the Gulf of Mexico	1/22/2013
Nexen Petroleum U.S.A. Inc., Structure Removal, SEA ES/SR 13–015.	Vermilion, Block 67, Lease OCS–G 00559, located 15 miles from the nearest Louisiana shoreline.	1/23/2013
Apex Oil & Gas, Inc., Structure Removal, SEA ES/SR 13–019	Vermillion, Block 129, Lease OCS–G 17898, located 31 miles from the nearest Louisiana shoreline.	1/23/2013
Nexen Petroleum U.S.A. Inc., Structure Removal, SEA ES/SR 13–016.	Vermillion, Block 66, Lease OCS–G 04787, located 14 miles from the nearest Louisiana shoreline.	1/23/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 97–143A.	Vermilion, Block 46, Lease OCS 00079, Located 8 miles from the nearest Louisiana shoreline.	1/24/2013
Walter Oil & Gas Corporation, Exploration Plan, SEA R–5766	South Timbalier 127, OCS Lease OCS–G 33109, located 22 miles from the nearest Louisiana shoreline.	1/25/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–017	South Marsh Island, Block 217, Lease OCS–G 00310, located 8 miles from the nearest Louisiana shoreline.	1/28/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–013 & 13–014.	South Marsh, Block 217, Lease OCS–G 00310, located 8 miles from the nearest Louisiana shoreline.	1/28/2013
Black Elk Energy Offshore Operations, LLC, Structure Removal, SEA ES/SR 13–005.	South Timbalier, Block 185, Lease OCS–G 01569, located 40 miles from the nearest Louisiana shoreline.	1/28/2013
WesternGeco, LLC, Geological & Geophysical Survey, SEA L12–001.	Central Planning Area of the Gulf of Mexico, Located 127 miles from the nearest shoreline.	1/29/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–012	South Marsh Island, Block 217, Lease OCS–G 00310, located 8 miles from the nearestLouisiana shoreline.	1/29/2013
Murphy Exploration & Production Company—USA, Exploration Plan, SEA S–7590.	Mississippi Canyon, Block 538, Lease OCS–G16614, & Mississippi Canyon, Block 582, Lease OCS–G 16623, located 37 miles from the nearest Louisiana shoreline.	1/30/2013
Merit Energy Company, LLC, Structure Removal, SEA ES/SR 13–004.	Galveston, Block 252, Lease OCS–G 11307, located 13 miles from the nearest Louisiana shoreline.	1/31/2013
Shell Offshore Inc., Exploration Plan, SEA R–5772	Mississippi Canyon, Block 809, Lease OCS–G 05868, located 50 miles from the nearest Louisiana shoreline.	1/31/2013
Dynamic Offshore Resources, LLC, Structure Removal, SEA ES/SR 12–325.	South Marsh Island, Block 109, Lease OCS–G 24873, located 68 miles from the nearest Louisiana shoreline.	1/31/2013
Nexen Petroleum U.S.A. Inc., Structure Removal, SEA ES/SR 13–025 & 13–026.	Vermilion, Block 66, Lease OCS–G 04787, located 15 miles from the nearest Louisiana shoreline.	1/31/2013
Anglo-Suisse Offshore Partners, LLC, Structure Removal, SEA ES/SR 06–112A.	West Delta, Block 117, Lease OCS–G 01101, located 23 miles from the nearest Louisiana shoreline.	1/31/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–020	Matagorda Island, Block 622, Lease OCS–G 05000, located 15 miles from the nearest Texas shoreline.	2/1/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 12–322 ..	Eugene Island, Block 314, Lease OCS–G 02111, located 73 miles from the nearest Louisiana shoreline.	2/4/2013
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 12–113.	Ship Shoal, Block 295, Lease OCS–G 21116, Located 58 miles from the nearest Louisiana shoreline.	2/4/2013
Dynamic Offshore Resources, LLC, Structure Removal, SEA ES/SR 13–031.	West Cameron, Block 290, Lease OCS–G 04818, located 27 miles from the nearest Louisiana shoreline.	2/4/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–033.	West Cameron, Block 45, Lease OCS 00299, located 7 miles from the nearest Louisiana shoreline.	2/4/2013
Statoil Gulf of Mexico LLC, Exploration Plan, SEA N–9669	Walker Ridge, Block 970, Lease Number OCS–G 26420, located 219 miles from the nearest Louisiana shoreline.	2/5/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–034.	West Cameron, Block 45, Lease OCS 00300, located 5 miles from the nearest Louisiana shoreline.	2/6/2013
Tesla Offshore, LLC, Geological & Geophysical Survey, SEA L12–010.	Central Planning Area of the Gulf of Mexico, located 4 miles from the nearest shoreline.	2/7/2013
Shell Offshore Inc., Geological & Geophysical Survey, SEA T12–004.	Alaminos Canyon, Western Planning Area of the Gulf of Mexico, located 124 miles from the nearest shoreline.	2/8/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–018	South Marsh Island, Block 218, Lease OCS–G 00310, located 9 miles from the nearest Louisiana shoreline.	2/11/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–029	West Cameron, Block 165, Lease OCS–G 00758, located 27 miles from the nearest Louisiana shoreline.	2/11/2013
TGS, Geological & Geophysical Survey, SEA L12–039	Central Planning Area of the Gulf of Mexico, located 80 miles from the nearest shoreline.	2/13/2013
Arena Offshore, LP, Structure Removal, SEA ES/SR 11–235 ..	Grand Isle, Block 102, Lease OCS–G 05662, located 47 miles from the nearest Louisiana shoreline.	2/14/2013

Activity/operator	Location	Date
Tana Exploration Company, LLC, Exploration Plan, SEA R–5797.	Central Planning Area of the Gulf of Mexico, located 66 miles from the nearest Louisiana shoreline.	2/15/2013
Nexen Petroleum U.S.A. Inc., Structure Removal, SEA ES/SR 13–040.	Vermilion, Block 66, Lease OCS–G 04787, located 15 miles from the nearest Louisiana shoreline.	2/15/2013
Dynamic Offshore Resources, LLC, Structure Removal, SEA ES/SR 13–036.	Ship Shoal, Block 188, Lease OCS–G 22712, located 32 miles from the nearest Louisiana shoreline.	2/19/2013
Shell Offshore Inc., Development Operations Coordination Document, SEA S–7584.	Green Canyon, Block 248, located 91 miles from the nearest Louisiana shoreline.	2/20/2013
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 13–039.	Eugene Island, Block 53, Lease OCS–G 00479, located 15 miles from the nearest Louisiana shoreline.	2/21/2013
Anadarko Petroleum Corporation, Exploration Plan, SEA R–5800.	Central Planning Area of the Gulf of Mexico, located 95 miles from the nearest Alabama shoreline.	2/22/2013
Eni US Operating Co. Inc., Development Operations Coordination Document, SEA S–7580.	Lease OCS–G 25142, in the Central Planning Area, located 101 miles from the nearest Louisiana shoreline.	2/22/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–041	South Timbalier, Block 52, Lease OCS–G 01241, located 13 miles from the nearest Louisiana shoreline.	2/26/2013
Union Oil Company of California, Exploration Plan, SEA R–5814.	Central Planning Area of the Gulf of Mexico, located 182 miles south of the nearest Louisiana shoreline.	2/27/2013
Chevron U.S.A. Inc., Exploration Plan, SEA R–5812	Central Planning Area of the Gulf of Mexico, located 185 miles from the nearest Louisiana shoreline.	2/27/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–042	South Timbalier, Block 51, Lease OCS–G 01240, located 11 miles from the nearest Louisiana shoreline.	2/27/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–044	South Timbalier, Block 51, Lease OCS–G 01240, located 12 miles from the nearest Louisiana shoreline.	2/27/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–045	West Cameron, Block 575, Lease OCS–G 04844, located 99 miles from the nearest Louisiana shoreline.	3/1/2013
Mariner Energy, Inc., Structure Removal, SEA ES/SR 13–011	West Cameron, Block 112, Lease OCS–G 21536, located 18 miles from the nearest Louisiana shoreline.	3/4/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–053.	East Cameron, Block 121, Lease OCS–G 22582, located 36 miles from the nearest Louisiana shoreline.	3/6/2013
Energy Partners, Ltd., Structure Removal, SEA ES/SR 13–052	South Timbalier, Block 185, Lease OCS–G 01569, located 40 miles from the nearest Louisiana shoreline.	3/6/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–046.	West Cameron, Block 45, Lease OCS–G 00300, located 4 miles from the nearest Louisiana shoreline.	3/6/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–048 & 13–049.	West Cameron, Block 575, Lease OCS–G 04844, located 99 miles from the nearest Louisiana shoreline.	3/6/2013
CGG Veritas (US) Inc., Geological & Geophysical Survey, SEA L13–002.	Green Canyon and Walker Ridge in the Central Planning Area of the Gulf of Mexico.	3/7/2013
Energy Partners, Ltd., Structure Removal, SEA ES/SR 12–170	South Timbalier, Block 46, Lease OCS–G 24955, located 11 miles from the nearest Louisiana shoreline.	3/7/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–043	South Timbalier, Block 51, Lease OCS–G 01240, located 10 miles from the nearest Louisiana shoreline.	3/11/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–050	West Cameron, Block 19, Lease OCS–G 21531, located 3 miles from the nearest Louisiana shoreline.	3/11/2013
Linder Oil Company, A Partnership, Structure Removal, SEA ES/SR 13–057.	East Cameron, Block 49, Lease OCS–G 00932, located 16 miles from the nearest Louisiana shoreline.	3/12/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–060.	West Cameron, Block 56, Lease OCS–G 00301, located 7 miles from the nearest Louisiana shoreline.	3/12/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 91–065.	West Cameron, Block 56, Lease OCS–G 00301, located 7 miles from the nearest Louisiana shoreline.	3/12/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–120	West Cameron, Block 645, Lease OCS–G 03973, located 115 miles from the nearest Louisiana shoreline.	3/12/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–055.	West Cameron, Block 45, Lease OCS–G 00300, located 4 miles from the nearest Louisiana shoreline.	3/13/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 06–128.	West Cameron, Block 56, Lease OCS–G 00301, located 7 miles from the nearest Louisiana shoreline.	3/13/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–056.	West Cameron, Block 56, Lease OCS–G 00301, located 7 miles from the nearest Louisiana shoreline.	3/13/2013
Walter Oil & Gas Corporation, Structure Removal, SEA ES/SR 09–155.	Main Pass, Block 313, Lease OCS–G 04127, located 16 miles from the nearest Louisisna shoreline.	3/14/2013
Pisces Energy LLC. Structure Removal, SEA ES/SR 13–047 ..	South Timbalier, Block 204, Lease OCS–G 16432, located 41 miles from the nearest Louisiana shoreline.	3/14/2013
Dynamic Offshore Resources, LLC, Structure Removal, SEA ES/SR 12–316.	Eugene Island, Block 309, Lease OCS–G 00997, located 70 miles from the nearest Louisiana shoreline.	3/15/2013
Tana Exploration Company LLC, Structure Removal, SEA ES/SR 12–182.	Eugene Island, Block 85, Lease OCS–G 24889, located 18 miles from the nearest Louisiana shoreline.	3/15/2013
Exxon Mobil Corporation, Structure Removal, SEA ES/SR 11–316.	Mississippi Canyon, Block 268, Lease OCS–G 02970, located 29 miles from the nearest Louisiana shoreline.	3/15/2013
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 13–037.	West Delta, Block 34, Lease OCS–G 03414, located 10 miles from the nearest Louisiana shoreline.	3/15/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–068.	South Timbalier, Block 21, Lease OCS 00263, located 5 miles from the nearest Louisiana shoreline.	3/18/2013
Magnum Hunter Production, Inc., Structure Removal, SEA ES/SR 11–206.	South Timbalier, Block 265, Lease OCS–G 12980, located 51 miles from the nearest Louisiana shoreline.	3/18/2013

Activity/operator	Location	Date
Mariner Energy Resources, Inc., Structure Removal, SEA ES/SR 12–114.	Vermilion, Block 375 Lease OCS–G 14427, located 98 miles from the nearest Louisiana shoreline.	3/18/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–027.	West Cameron, Block 45, Lease OCS 00299, located 5 miles from the nearest Louisiana shoreline.	3/18/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–028.	West Cameron, Block 45, Lease OCS 00300, located 5 miles from the nearest Louisiana shoreline.	3/18/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–071.	South Timbalier, Block 21, Lease OCS 00263, located 3 miles from the nearest Louisiana shoreline.	3/19/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–024	South Timbalier, Block 51, Lease OCS–G 01240, located 10 miles from the nearest Louisiana shoreline.	3/19/2013
Apache Corporation, Structure Removal, SEA ES/SR 07–137	West Cameron, Block 148, Lease OCS–G 02640, located 12 miles from the nearest Louisiana shoreline.	3/19/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–051.	West Cameron, Block 45, Lease OCS–G 00300, located 5 miles from the nearest Louisiana shoreline.	3/19/2013
Tana Exploration Company LLC, Structure Removal, SEA ES/SR 13–064.	Main Pass, Block 99, Lease OCS–G 21703, located 18 miles from the nearest Louisiana shoreline.	3/21/2013
Shell Offshore Inc., Exploration Plan, SEA R–5826	Mississippi Canyon, Block 809, Lease OCS–G 05868, located 54 miles south of the nearest Louisiana shoreline.	3/21/2013
Apache Corporation, Structure Removal, SEA ES/SR 12–115	Ship Shoal, Block 296, Lease OCS–G 15303, located 60 miles from the nearest Louisiana shoreline.	3/21/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–072.	South Timbalier, Block 21, Lease OCS 00263, located 3 miles from the nearest Louisiana shoreline.	3/21/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–069.	South Timbalier, Block 22, Lease OCS 00165, located 6 miles from the nearest Louisiana shoreline.	3/21/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–075.	South Timbalier, Block 28, Lease OCS–G 01362, located 6 miles from the nearest Louisiana shoreline.	3/21/2013
Statoil Gulf of Mexico LLC, Exploration Plan, SEA R–5824	Walker Ridge, Block 970, Lease OCS–G 26420, located 218 miles from the nearest Louisiana shoreline.	3/21/2013
Merit Energy Company, LLC, Structure Removal, SEA ES/SR 13–081.	Eugene Island, Block 159, Lease OCS–G 23867, located 38 miles from the nearest Louisiana shoreline.	3/22/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 98–012	Vermilion, Block 24, Lease OCS–G 03543, located 4 miles from the nearest Louisiana shoreline.	3/22/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–038	West Cameron, Block 294, Lease OCS–G 04090, located 29 miles from the nearest Louisiana shoreline.	3/22/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–076.	West Cameron, Block 45, Lease OCS–G 00300, located 5 miles from the nearest Louisiana shoreline.	3/22/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–062	Main Pass, Block 40, Lease OCS–G 00373, located 11 miles from the nearest Louisiana shoreline.	3/25/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–063	Main Pass, Block 41, Lease OCS–G 00374, located 10 miles from the nearest Louisiana shoreline.	3/25/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–061	Main Pass, Block 41, Lease OCS–G 00374, located 11 miles from the nearest Louisiana shoreline.	3/25/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–058	South Marsh Island, Block 237, Lease OCS–G 00310, located 11 miles from the nearest Louisiana shoreline.	3/25/2013
Union Oil Company of California, Structure Removal, SEA ES/SR 13–065 & 13–066.	West Cameron, Block 196, Lease OCS–G 05292, located 31 miles from the nearest Louisiana shoreline.	3/25/2013
Apache Corporation, Structure Removal, SEA ES/SR 13–082	Eugene Island, Block 296, Lease OCS–G 02105, located 60 miles from the nearest Louisiana shoreline.	3/26/2013
Chevron U.S.A. Inc., Structure Removal, SEA ES/SR 13–059	South Marsh Island, Block 237, Lease OCS–G 00310, located 11 miles from the nearest Louisiana shoreline.	3/26/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–070.	South Timbalier, Block 21, Lease OCS 00263, located 3 miles from the nearest Louisiana shoreline.	3/26/2013
Rooster Petroleum, LLC, Structure Removal, SEA ES/SR 04–135.	Eugene Island, Block 28, Lease OCS–G 05479, located 13 miles from the nearest Louisiana shoreline.	3/27/2013
Mariner Energy, Inc., Structure Removal, SEA ES/SR 11–219	Eugene Island, Block 325, Lease OCS–G 05517, located 63 miles from the nearest Louisiana shoreline.	3/27/2013
Apache Corporation, Structure Removal, SEA ES/SR 11–163	South Pass, Block 52, Lease OCS–G 23698, located 8 miles from the nearest Louisiana shoreline.	3/27/2013
Energy XXI GOM, LLC, Structure Removal, SEA ES/SR 13–073.	South Timbalier, Block 21, Lease OCS 00263, located 5 miles from the nearest Louisiana shoreline.	3/27/2013
Stone Energy Corporation, Structure Removal, SEA ES/SR 13–077.	West Cameron, Block 45, Lease OCS–G 00300, located 4 miles from the nearest Louisiana shoreline.	3/27/2013
JX Nippon Oil Exploration (U.S.A.) Limited, Structure Removal, SEA ES/SR 12–096.	West Cameron, Block 551, Lease OCS–G 02555, located 95 miles from the nearest Louisiana shoreline.	3/27/2013
McMoRan Oil & Gas LLC, Structure Removal, SEA ES/SR 13–085.	Brazos, Block A23, Lease OCS–G 32731, located 35 miles from the nearest Texas shoreline.	3/28/2013
McMoRan Oil & Gas LLC, Structure Removal, SEA ES/SR 13–080.	Mustang Island, Block 782, Lease OCS–G 10147, located 26 miles from the nearest Texas shoreline.	3/28/2013
Union Oil Company of California, Structure Removal, SEA ES/SR 13–079.	West Cameron, Block 197, Lease OCS–G 03264, located 31 miles from the nearest Louisiana shoreline.	3/28/2013
McMoRan Oil & Gas LLC, Structure Removal, SEA ES/SR 13–088.	High Island, Block A472, Lease OCS–G 17182, located 82 miles from the nearest Texas shoreline.	3/29/2013
McMoRan Oil & Gas LLC, Structure Removal, SEA ES/SR 13–089.	South Marsh Island, Block 49, Lease OCS–G 00787, located 50 miles from the nearest Louisiana shoreline.	3/29/2013

Activity/operator	Location	Date
ATP Oil & Gas Corporation, Structure Removal, SEA ES/SR 13–096.	South Timbalier, Block 77, Lease OCS–G 04827, located 18 miles from the nearest Louisiana shoreline.	3/29/2013
McMoRan Oil & Gas LLC, Structure Removal, SEA ES/SR 13–086.	West Cameron, Block 192, Lease OCS 00190, located 28 miles from the nearest Louisiana shoreline.	3/29/2013
McMoRan Oil & Gas LLC, Structure Removal, SEA ES/SR 13–083.	West Cameron, Block 294, Lease OCS–G 04090, located 28 miles from the nearest Louisiana shoreline.	3/29/2013

Persons interested in reviewing environmental documents for the proposals listed above or obtaining information about the SEAs and FONSIs prepared by the Gulf of Mexico OCS Region are encouraged to contact BOEM at the address or telephone listed in the **FOR FURTHER INFORMATION CONTACT** section.

Dated: April 12, 2013.

John L. Rodi

Regional Director Gulf of Mexico OCS Region.

[FR Doc. 2013–11079 Filed 5–9–13; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Outer Continental Shelf (OCS) Geological and Geophysical Exploration Activities in the Gulf of Mexico

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Intent; Notice of Scoping Meetings; and Request for Scoping Comments.

SUMMARY: Pursuant to the regulations implementing (National Environmental Policy Act) (NEPA), and subject to available funding, BOEM is announcing the intent to prepare a Programmatic Environmental Impact Statement (PEIS) to evaluate potential environmental effects of multiple geological and geophysical (G&G) activities in OCS waters of the Gulf of Mexico (GOM), extending from the coastline to the seaward boundary of the Exclusive Economic Zone (EEZ), including the GOM OCS. The PEIS will be prepared cooperatively with NMFS to serve as the requisite environmental analysis under NEPA for the National Marine Fisheries Service's (NMFS) Marine Mammal Protection Act (MMPA) rulemaking governing authorization for unintentional marine mammal takes during G&G activities in GOM waters. It will also provide information for future decisions regarding Outer Continental Shelf Lands Act (OCSLA) permit and MMPA authorization actions, in addition to informing consultations under the Endangered Species Act (ESA), Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA), and other statutes. By this document, BOEM announces: The intention to prepare a PEIS; commencement of the scoping process under NEPA; a request for public comment on the scope of the PEIS; times, dates and locations for public scoping meetings; and a request for other Federal Agencies, and State, Tribal, and local governments to consider becoming cooperating agencies in the preparation of the PEIS.

DATES: Comments should be submitted no later than June 24, 2013. For specific meeting dates and more information on submitting comments, see **ADDRESSES**.

ADDRESSES: The following public scoping meetings are planned for the PEIS:

- *Tampa, Florida:* Monday, June 10, 2013, Embassy Suites Westshore Tampa Airport Hotel, 555 North Westshore Boulevard, Tampa, Florida 33609; one meeting beginning at 6:30 p.m. EDT;
- *Fort Walton Beach, Florida:* Tuesday, June 11, 2013, Ramada Plaza Beach Resort, 1500 Miracle Strip Parkway SE., Fort Walton Beach, Florida 32548; one meeting beginning at 6:30 p.m. CDT;
- *Mobile, Alabama:* Wednesday, June 12, 2013, Government Plaza, 205 Government Street, Mobile, Alabama 36644; one meeting beginning at 6:30 p.m. CDT;
- *Gulfport, Mississippi:* Thursday, June 13, 2013, Courtyard by Marriott Gulfport Beachfront MS Hotel, 1600 East Beach Boulevard, Gulfport, Mississippi 39501; one meeting beginning at 6:30 p.m. CDT;
- *Galveston, Texas:* Monday, June 17, 2013, Galveston Hilton, 5400 Seawall Boulevard, Galveston, Texas 77551; one meeting beginning at 6:30 p.m. CDT;
- *New Orleans, Louisiana:* Wednesday, June 19, 2013, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123; one meeting beginning at 1 p.m. CDT;
- *Silver Spring, Maryland:* Thursday, June 20, 2013, National Oceanic and Atmospheric Administration, 1305 East-West Highway, Silver Spring, Maryland 20910; one meeting beginning at 1:00 p.m. EDT.

Comments: Statements, both oral and written, will be received at the scoping meetings. All persons wishing to speak will have an opportunity to do so. Time limits may be set on speakers to allow time for all speakers to participate. In addition, background information will be provided by BOEM and NMFS on the Federal compliance processes related to this Proposed Action.

In lieu of participation in the scoping meetings listed above, Federal, State, and local government agencies and other interested parties, including members of the public, may submit written comments on the scope of the PEIS, significant issues that should be addressed, alternatives that should be considered, and the types of G&G activities and geographical areas of interest on Federal and State waters of the GOM. Comments will also be shared with NMFS.

Comments may be submitted in one of the following three ways:

1. In written form enclosed in an envelope labeled ''Comments on Scoping for the Gulf of Mexico G&G PEIS'' and mailed (or hand carried) to Mr. Gary D. Goeke, Chief, Regional Assessment Section, Office of Environment (MS 5410), Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394; or
2. Electronically to the BOEM email address: *gomggeis@boem.gov.*
3. Through the regulations.gov web portal: Navigate to *http://www.regulations.gov* and search for ''Geological and Geophysical Exploration Activities on Federal and State Waters of the Gulf of Mexico'' (Note: It is important to include the quotation marks in your search terms.) Click on the ''Comment Now!'' button to the right of the document link. Enter your information and comment, then click ''Submit''.

Public Disclosure of Names and Addresses: Before including your address, phone number, email address, or other personal identifying information in your comment, be advised 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 from public review your personal identifying information, we cannot guarantee that we will be able to do so.

For further information regarding the GOM G&G PEIS, please visit our Web site at: *http://www.boem.gov/GOM–G–G–PEIS/*

FOR FURTHER INFORMATION CONTACT: For information on this notice or the public scoping meetings, please contact Ms. Beth Nord, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard (GM 623E), New Orleans, Louisiana 70123–2394, telephone (504) 736–2995. For information on BOEM's policies associated with this notice, please contact Mr. Gary Goeke, Section Chief, Regional Assessment Section, Office of Environment (GM 623E), Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394, telephone (504) 736–3233. For information on NMFS' policies associated with this notice, please contact Mr. Howard Goldstein, Office of Protected Resources, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, 1315 East-West Highway, Silver Spring, Maryland 20910, telephone (301) 427–8401.

SUPPLEMENTARY INFORMATION: Scoping is the initial step in the NEPA process. BOEM will fully comply with all pertinent laws, rules, and regulations and will allow the public an adequate opportunity to participate in the NEPA process, including scoping meetings and public comment periods. The publication of this NOI initiates the scoping process and 45-day scoping comment period for this PEIS. The public scoping meetings will be held during this 45-day timeframe. The activities considered within this PEIS are associated with GOM OCS oil and gas exploration and development, siting for potential renewable energy projects, and marine minerals extraction; they could take place over a period of up to ten years. The purpose of the scoping meetings will be to provide stakeholders with more information on the Federal compliance processes related to the proposed actions, and solicit comments on the scope of the PEIS. Under the Proposed Action, BOEM proposes to issue permits to conduct G&G activities under OCSLA and NMFS proposes to promulgate regulations under the MMPA that establish a framework for issuing letters of authorization for the unintentional take of marine mammals incidental to G&G activities in GOM waters.

Through the scoping process, Federal, State and local government agencies and other interested parties have the opportunity to assist in determining the significant issues and alternatives for analysis in the PEIS, and developing the scope of the PEIS. This early planning and consultation step is important to ensure all interests and concerns are communicated to BOEM and NMFS as the PEIS is developed.

Background: A variety of G&G techniques are used to characterize the geological structure of the OCS slope and deepwater ocean environments. Geological and geophysical surveys are conducted to: (1) Obtain data for hydrocarbon exploration and production; (2) aid in siting renewable energy structures; (3) locate potential sand and gravel resources; (4) identify possible seafloor or shallow depth geologic hazards; and (5) locate potential archaeological resources and potential hard bottom habitats for avoidance. The selection of a specific G&G technique or suite of techniques is driven by data needs and the target of interest. The following types of G&G activities will be included in the PEIS: (1) Various types of deep penetration seismic airgun surveys used almost exclusively for oil and gas exploration and development; (2) other types of surveys and sampling activities used only in support of oil and gas exploration and development, including electromagnetic surveys, deep stratigraphic and shallow test drilling, and various remote sensing methods; (3) high-resolution geophysical (HRG) surveys used in three program areas (oil and gas, renewable energy, and marine minerals) to detect geohazards, archaeological resources, and certain types of benthic communities; and (4) geological and geotechnical bottom sampling used in all three program areas to assess the suitability of seafloor sediments for supporting structures (e.g., platforms, pipelines, cables, wind turbines) or to evaluate the quantity and quality of sand for beach nourishment projects.

The GOM OCS area that will be analyzed within the GOM G&G PEIS is illustrated in Figure 1 as the GOM Western, Central, and Eastern Planning Areas. This Area of Interest (AOI) includes State waters and extends from the coastline (excluding estuaries) through Federal waters of the OCS out to the seaward boundary of the EEZ.

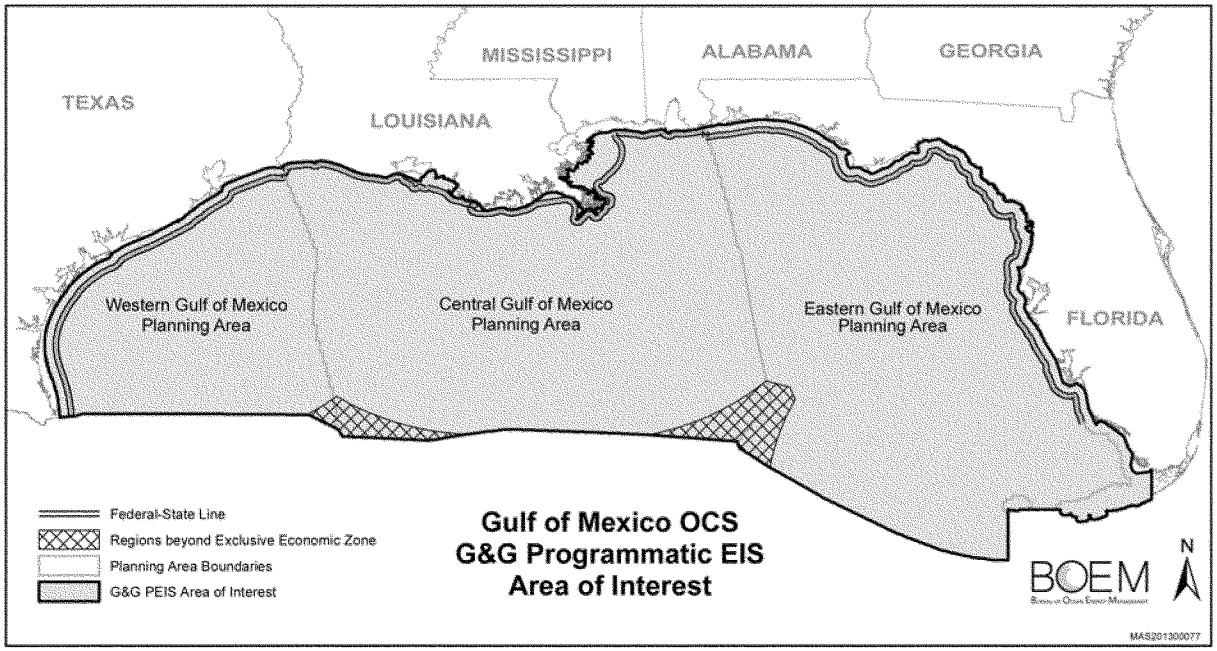


Figure 1. The proposed AOI to be analyzed in the PEIS.

The PEIS will evaluate the environmental impacts to resources in Federal and State waters of the GOM resulting from G&G activities taking place either exclusively in Federal waters or in both Federal and State waters (but not exclusively in State waters), subject to BOEM and NMFS regulatory authority that may be proposed over a period of up to ten years. While State waters are not within BOEM's jurisdiction, NMFS has jurisdiction and permitting authority in both Federal and State waters. The AOI encompasses adjacent State waters for three reasons: (1) NMFS requires an assessment of potential impacts to resources under its jurisdiction; (2) G&G activities under all three program areas (oil and gas, renewable energy, and marine minerals) could include survey areas that include Federal and State waters; and (3) the potential adverse effects associated with G&G activities introduced into the environment during OCS G&G surveys could affect resources in State waters. Surveys occurring exclusively in State waters are not considered in the scope of this PEIS.

The PEIS is intended to serve as the primary NEPA environmental analysis to support future OCSLA and MMPA permitting decisions. However, should BOEM or NMFS determine there is a need to develop a future site-specific analysis, e.g., an EIS or environmental assessment for a particular G&G activity, the PEIS would serve as a reference document to implement the ''tiering'' objective detailed in NEPA's implementing regulations (40 CFR 1502.20). The proposed G&G activities include, but are not limited to, deep-penetration and high resolution seismic surveys, electromagnetic surveys, magnetic surveys, gravity surveys, remote sensing surveys, marine vibrator surveys, and geological and geochemical sampling. These activities would provide information about the location and extent of oil and gas reserves, bottom conditions for oil and gas or renewable energy installations, and suitable locations of marine minerals off the Gulf coast of the U.S. Up-to-date and state-of-the-art G&G data and information are required for business decisions in furtherance of prospecting for OCS oil and gas in an orderly manner, assessing sites for renewable energy facilities, or developing marine mineral resources.

The alternatives that will be analyzed in the PEIS have not been finalized yet. The alternatives will include the Proposed Action (BOEM proposes to issue permits to conduct G&G activities under OCSLA and NMFS proposes to engage in a rulemaking under the MMPA and issue letters of authorization to allow the unintentional marine mammal takes during G&G activities in GOM waters), the No Action Alternative, and other alternatives that may include (but are not limited to) variations on the Proposed Action involving monitoring and mitigation measures and restrictions. The public is invited to suggest additional alternatives, including mitigation and monitoring measures, for our agencies' consideration and possible inclusion in the PEIS (40 CFR 1508.22(a)).

In conjunction with the preparation of the PEIS, the BOEM has asked NMFS to complete MMPA rulemaking for incidental take (by harassment) of marine mammal species in the GOM as a result of G&G survey from oil and gas activities. Under the MMPA (16 U.S.C. 1371; 50 CFR Subpart 216), the taking of marine mammals without a permit or exemption from NMFS is prohibited. The PEIS will be prepared cooperatively with NMFS to provide the necessary documentation under NEPA to support decisions regarding future OCSLA permit and MMPA authorization actions, in addition to complying with other statutes such as the ESA and the MSFCMA.

In the interim, BOEM continues to review proposed G&G seismic activities and non-commercial sand and gravel prospecting activities. BOEM issues permits for G&G seismic activities and provides authorization for non-commercial sand search (marine minerals program) only after these activities have been evaluated under NEPA and reviewed following interim project-specific consultation procedures under the ESA between BOEM and NMFS.

More information on G&G activities can be found on pages 13–15 of BOEM's *Leasing Oil and Natural Gas Resources: Outer Continental Shelf* (see *http://www.boem.gov/search-results.aspx?q=GreenBook-LeasingDocument.pdf+* and BOEM's

Geological and Geophysical Exploration for Mineral Resources on the Gulf of Mexico Outer Continental Shelf: Final Programmatic Environmental Assessment (see *http://www.boem.gov/Oil-and-Gas-Energy-Program/GOMR/2004–054.aspx*).

Cooperating Agency: BOEM invites other Federal agencies and State, Tribal, and local governments to consider becoming cooperating agencies in the preparation of the PEIS. We invite qualified government entities to inquire about cooperating agency status for the PEIS. 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 note 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 the availability of pre-decisional information. BOEM anticipates this summary will form the basis for a Memorandum of Agreement (MOA). Agencies should also consider 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 NEPA.* A copy of this document is available at:*http://ceq.hss.doe.gov/nepa/regs/cooperating/cooperatingagenciesmemorandum.html* and/or *http://ceq.hss.doe.gov/nepa/regs/cooperating/cooperatingagencymemofactors.html* BOEM and NMFS, as co-agencies, will not provide financial assistance to any other cooperating agencies. Even if an organization is not an official cooperating agency, opportunities exist to provide information and comments during the normal public input phases of the NEPA/PEIS process. If further information about cooperating agencies is needed, please contact Mr. Gary Goeke at (504) 736–3233.

Authority: 42 U.S.C. 4321 *et seq.,* 43 U.S.C. 1331–1356a, 16 U.S.C. 1361 *et seq.,* 40 CFR 1501.7

Dated: May 6, 2013.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2013–11226 Filed 5–9–13; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Notice on Outer Continental Shelf Oil and Gas Lease Sales

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: List of restricted joint bidders.

SUMMARY: Pursuant to the authority vested in the Director of the Bureau of Ocean Energy Management by the joint bidding provisions of 30 CFR 556.41, each entity within one of the following groups shall be restricted from bidding with any entity in any of the other following groups at Outer Continental Shelf oil and gas lease sales to be held during the bidding period May 1, 2013, through October 31, 2013. This List of Restricted Joint Bidders will cover the period May 1, 2013, through October 31, 2013, and replace the prior list published on October 23, 2012, which covered the period of November 1, 2012, through April 30, 2013.

Group I. BP America Production Company
- BP Exploration & Production Inc.
- BP Exploration (Alaska) Inc.

Group II. Chevron Corporation
- Chevron U.S.A. Inc.
- Chevron Midcontinent, L.P.
- Unocal Corporation
- Union Oil Company of California
- Pure Partners, L.P.

Group III. Eni Petroleum Co. Inc.
- Eni Petroleum US LLC
- Eni Oil US LLC
- Eni Marketing Inc.
- Eni BB Petroleum Inc.
- Eni US Operating Co. Inc.
- Eni BB Pipeline LLC

Group IV. Exxon Mobil Corporation
- ExxonMobil Exploration Company

Group V. Petrobras America Inc.
- Petroleo Brasileiro S.A.

Group VI. Shell Oil Company
- Shell Offshore Inc.
- SWEPI LP
- Shell Frontier Oil & Gas Inc.
- SOI Finance Inc.
- Shell Gulf of Mexico Inc.

Group VII. Statoil ASA
- Statoil Gulf of Mexico LLC
- Statoil USA E&P Inc.
- Statoil Gulf Properties Inc.

Group VIII. Total E&P USA, Inc.

Dated: April 29, 2013.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2013–11076 Filed 5–9–13; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Resource Conservation and Recovery Act

On April 26, 2013, the Department of Justice lodged a proposed consent decree with the United States District Court for the Northern District of Ohio in the lawsuit entitled *United States* v. *Schott Metal Products, Inc. and The Estate of Samuel Schott,* Civil Action No. 5:13-cv-00950.

In the Complaint filed in this action the United States alleged that Defendants failed to comply with a 2006 Administrative Order issued by the United States Environmental Protection Agency (''EPA'') to sample and monitor soil and groundwater at the Schott Metal Products, Inc. facility in Akron, Ohio, in violation of Section 3013(a) of the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6934(a). The proposed consent decree requires Defendants to comply with the 2006 Administrative Order by implementing a ''work plan,'' and an addendum thereto, recently approved by EPA. The proposed consent decree further requires Defendants to pay a civil penalty of $375,000, for the alleged failure to timely comply with the 2006 Administrative Order.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Schott Metal Products, Inc. and The Estate of Samuel Schott,* D.J. Ref. No. 90–7–1–09982. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	pubcomment-ees.enrd@usdoj.gov.
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $44.25 (with all attachments) or $9.00 (without attachments) (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Chief Management, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2013–11107 Filed 5–9–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—3D PDF Consortium, Inc.

Notice is hereby given that, on April 19, 2013, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), 3D PDF Consortium, Inc. (''3D PDF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, INTRATECH Corporation, Mapo-gu, Seoul, REPUBLIC OF KOREA, has been added as a party to this venture. In addition, Boeing Shared Services Group has changed its name to The Boeing Company, Seattle, WA.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and 3D PDF intends to file additional written notifications disclosing all changes in membership.

On March 27, 2012, 3D PDF filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 20, 2012 (77 FR 23754).

The last notification was filed with the Department on November 8, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on December 4, 2012 (77 FR 71831).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2013–11113 Filed 5–9–13; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–1]

Jose G. Zavaleta, M.D.; Decision and Order

On May 10, 2012, Administrative Law Judge Gail A. Randall issued the attached Recommended Decision.[1] Neither party filed exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and recommended sanction, except for her discussion that the findings of a prior agency order denying a previous application filed by Respondent, *see Jose Gonzalo Zavaleta,* 76 FR 49506 (2011), were not entitled to *res judicata* effect because they were issued in a proceeding in which Respondent waived his right to a hearing. ALJ at 12–13 (citing *Robert M. Golden,* 65 FR 5663 (2000)). While the ALJ was bound by the existing Agency precedent on the issue, I conclude that a re-examination of the issue is warranted and overrule *Golden.* However, because this has no effect on the outcome, I will adopt the ALJ's recommended sanction and will order that Respondent's application for a DEA Certificate of Registration as a practitioner be denied.

The ALJ's Ruling on Whether the Prior Agency Order Denying Respondent's Application Is Entitled to *Res Judicata* Effect

On February 23, 2009, the Deputy Assistant Administrator, DEA Office of Diversion Control, issued an Order to Show Cause to Respondent which proposed the denial of the application for registration submitted by him on July 28, 2008. *See Jose Gonzalo Zavaleta,* 76 FR at 49506. The Show Cause Order was based on allegations that Respondent had issued multiple controlled-substance prescriptions to undercover officers (UCs) and that he lacked a legitimate medical purpose and violated federal law in doing so because he either performed a cursory medical examination or failed to perform any medical examination. *Id.* Respondent failed to request a hearing on the allegations. *Id.*

On July 27, 2011, this Agency issued a Decision and Order denying the application which Respondent submitted on July 28, 2008. *Id.* at 49508. The Agency's denial of Respondent's application was based on the evidence submitted by the Government showing that two officers from the Louisiana State Police had made undercover visits to Respondent on various occasions, during which they obtained from him prescriptions for controlled substances including hydrocodone, alprazolam, and Phenergan with codeine. *Id.* With respect to UC1, who visited him on January 23, 2008, the evidence showed that he asked Respondent for Lortab and initially denied that he was in pain; nonetheless, Respondent issued him a prescription for Lortab after UC1 stated (falsely) that he had a sexually transmitted disease, and that Respondent did so without performing a physical examination. *Id.* at 49506.

Likewise, with respect to UC2, the Agency found that while she initially denied being in pain, Respondent prescribed hydrocodone to her. *Id.* Moreover, on a subsequent visit, Respondent prescribed Phenergan, a narcotic cough syrup, even though UC2 had no symptoms of cough or congestion, as well as more hydrocodone. *Id.* Finally, at UC2's third visit, Respondent prescribed hydrocodone as well as Xanax to her. *Id.* At no time did Respondent obtain UC2's medical records or perform a physical examination on her. *Id.* Rather, Respondent coached UC2 as to what to say to justify the issuance of the prescriptions. *Id.*

Based on these findings, the Agency concluded that Respondent had failed to establish a physician-patient relationship with the UCs and therefore lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he prescribed controlled substances to them. *Id.* at 49508 (citing 21 U.S.C. 1306.04(a); 21 U.S.C. 841(a)(1); *Louisiana* v. *Moody,* 393 So.2d 1212, 1215 (La. 1981)).

During the course of the instant proceeding, the ALJ directed the parties to address ''whether the doctrine of *res judicata* applies to the Final Order'' and ''thus bar[s] Respondent from 'relitigat[ing] the factual findings and conclusions of law of the prior proceeding.' '' ALJ at 12. (quoting *Robert*

[1] All citations to the Recommended Decision are to the ALJ's slip opinion.

L. Dougherty, 76 FR 16823, 16830 (2011)). Both parties filed briefs, with the Government seeking partial summary disposition on this basis.

The ALJ denied the Government's motion, holding that while ''the factual findings in DEA final orders are entitled to *res judicata*[,] . . . the Agency has also expressly limited the application of *res judicata,* refusing to apply the principle when the final order was issued without an evidentiary hearing.'' ALJ at 12–13 (citing *Golden,* 65 FR at 5664). Noting that the July 27, 2011 Final Order denying Respondent's first application was based ''solely on . . . material in the [Agency's] investigative file and not [issued] following an evidentiary hearing,'' the ALJ held that ''the factual findings and legal conclusion contained in the Final Order were not entitled to *res judicata* effect in this matter.'' *Id.* at 13.

In holding that the factual findings and legal conclusions of the July 2011 Order were not entitled to preclusive effect, the ALJ properly applied *Golden.* Indeed, the ALJ was bound by *Golden.* However, given *Golden*'s cursory discussion of the issue, I conclude that a re-examination of its holding is warranted. While there is support for the rule established in *Golden,* it is clear that its rule is not constitutionally required. Moreover, there is a substantial body of authority which supports the view that as long as the Agency previously provided a party with a full and fair opportunity to litigate the allegations which supported the Agency's proposed action (whether the denial of an application or revocation of a registration), a party's failure to avail itself of that opportunity does not prohibit the Agency from giving preclusive effect to the factual findings and conclusions of law rendered in the prior proceeding.

As the Supreme Court has held, '' '[w]hen an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata* to enforce repose.' '' *United States* v. *Utah Constr. & Mining Co.,* 384 U.S. 394, 421–22 (1966) (as quoted in *University of Tennessee* v. *Elliot,* 478 U.S. 788, 797–98 (1986)). In *Elliot,* the Court further explained that ''giving preclusive effect to administrative factfinding serves the value underlying general principles of collateral estoppel,'' namely ''avoiding the cost and vexation of repetitive litigation and the public's interest in conserving judicial resources.'' *Id.* at 798 (citations omitted). Thus,

> [w]here an administrative forum has the essential procedural characteristics of a court, its determinations should be accorded the same finality that is accorded the judgment of a court. The importance of bringing a legal controversy to conclusion is generally no less when the tribunal is an administrative tribunal than when it is a court.

Id. at n.6 (quoting Restatement (Second) of Judgments § 83, p. 269 (1982) [hereinafter, Restatement]).

The Restatement sets forth five requirements which an adjudicative determination issued by an administrative tribunal must satisfy for it to be entitled to *res judicata* effect. These are that the proceeding provide:

> (a) Adequate notice to persons who are to be bound by the adjudication . . . ;
>
> (b) The right on behalf of a party to present evidence and legal argument in support of the party's contentions and fair opportunity to rebut evidence and argument by opposing parties;
>
> (c) A formulation of issues of law and fact in terms of the application of the rules with respect to specified parties concerning a specific transaction, situation, or status, or a specific series thereof;
>
> (d) A rule of finality, specifying a point in the proceeding when presentations are terminated and a final decision is rendered; and
>
> (e) Such other procedural elements as may be necessary to constitute the proceeding a sufficient means of conclusively determining the matter in question, having regard for the magnitude and complexity of the matter in question, the urgency with which the matter must be resolved, and the opportunity of the parties to obtain evidence and formulate legal contentions.

Restatement, § 83.

DEA's proceedings meet each of these requirements. First, under 21 U.S.C. 824(c), the Agency is required to ''serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended,'' which ''shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order.'' *See also* 21 CFR 1301.37(c) (''The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.'').

Moreover, ''[p]roceedings to deny, revoke, or suspend shall be conducted pursuant to this section *in accordance with subchapter II of chapter 5 of Title 5.*'' 21 U.S.C. 824(c) (emphasis added). The latter are the provisions of the Administrative Procedure Act governing the conduct of adjudicatory proceedings, and which provide, *inter alia,* that the hearing be conducted by an administrative law judge, whose powers include the issuance of subpenas, and that ''[a] party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.'' 5 U.S.C. 556(c) & (d). In addition, DEA regulations set forth additional procedural protections to ensure the fairness of the hearing and specify the point at which the proceeding becomes final. *See* 21 CFR 1316. Thus, proceedings conducted under sections 303 and 304 of the Controlled Substance Act (21 U.S.C. 823 & 824) clearly meet each of these requirements.

Respondent does not dispute that he was served with an Order to Show Cause proposing the denial of his first application and that he failed to respond to the Order and thus waived his right to a hearing. Resp. Memorandum, at 3. Rather, Respondent asserts that the previous Final Order denying his application should not be given preclusive effect because he falls within one of the *res judicata* doctrine's recognized exceptions. *Id.*

More specifically, Respondent argues that ''[t]here is a clear and convincing need for a new determination of the issue'' for two reasons. *Id.* at 2 (quoting Restatement § 28). First, he invokes the exception which provides for relitigation ''because of the potential adverse impact of the determination on the public interest or the interest of persons not themselves parties in the initial action.'' *Id.* (quoting Restatement § 28). Second, he invokes the exception which provides for relitigation where ''the party sought to be precluded, as a result of the conduct of his adversary or other special circumstances, did not have an adequate opportunity or incentive to obtain a full and fair adjudication in the initial action.'' *Id.* at 3 (quoting Restatement § 28).

With respect to the first exception, Respondent argues that ''[h]e has been an asset in every community where he has practiced medicine'' and that his ''patients and the public interest, especially in the community where he practices medicine, have been adversely affected since he lost his ability to prescribe controlled substances.'' *Id.* at 5. Respondent thus contends that ''[i]f the doctrine of res judicata is applied in these proceedings and [his application] is denied, then the public interest will be affected in that [his] experience as a physician cannot be properly utilized because many of the employment opportunities available to him require a . . . registration.'' *Id.*

DEA has held, however, that evidence as to the impact on the community of a practitioner's lack (or loss) of a registration is not relevant under any of the factors of the public interest standard of 21 U.S.C. 823(f). *See Gregory D. Owens,* 74 FR 36751, 36756–57 & n.22 (2009).[2] *See also Kwan Bo Jin,* 77 FR 35021, 35021 (2012); *Linda Sue Cheek,* 76 FR 66972, 66973 (2011); *Mark De La Lama,* 76 FR 20011, 20020 n.20 (2011); *Bienvenido Tan,* 76 FR 17673, 17694 n.58 (2011). Because such evidence is not relevant in assessing whether Respondent's registration would be ''consistent with the public interest,'' 21 U.S.C. 823(f), this exception cannot support allowing Respondent to relitigate the issues decided by the July 2011 Order.

As for the second exception, Respondent asserts that ''he filed [his first Application] prematurely and did not follow the advice of his [former] counsel.'' Resp. Memorandum, at 4. He further argues that while he ''wanted to respond to the Order to Show Cause,'' which was issued in response to his first application, ''this time he followed the advice of his counsel which . . . advised him not to respond and wait until he completed his pretrial intervention program and [the] requirements placed on him by the Louisiana State Board of Medical Examiners.'' *Id.* Respondent thus contends that ''this is a special circumstance which did not give him an adequate opportunity or incentive to obtain a full and fair adjudication in the initial action,'' and that ''[i]f he had been informed by counsel of the consequences of not responding, [he] would have responded regardless of the outcome in order to put his evidence into the record.'' *Id.*

In the civil context, however, courts generally do not overturn judgments simply because a party complied with legal advice that was erroneous or ultimately proved to be disadvantageous. *Cf. Nelson* v. *The Boeing Co.,* 446 F.3d 1118, 1120 (10th Cir. 2006) (declining to recognize right to effective assistance of counsel in civil suit outside of immigration context). And in any event, the Show Cause Order issued in the first proceeding fully explained that the consequence of Respondent's failure to request a hearing would include that he would be deemed to have waived his right to a hearing and that a final order would be issued ''based upon the investigative file and record of this proceeding as it may then appear.'' Order to Show Cause (Feb. 23, 2009) (ALJ Ex. 1, at 5).

Moreover, as the comment to this exception states, while ''the court in the second proceeding may conclude that issue preclusion should not apply because the party sought to be bound did not have an adequate opportunity or incentive to obtain a full and fair adjudication in the first proceeding[,] [s]uch a refusal to give the first judgment preclusive effect should not occur without a compelling showing of unfairness, nor should it be based simply on a conclusion that the first determination was patently erroneous.'' Restatement § 28, cmt. j.[3] Respondent's contention that he did not challenge the first Show Cause Order because he relied on the disadvantageous advice of his prior attorney does not make for a ''compelling showing of unfairness.'' *Id.*

The ALJ further rejected as ''illogical'' and contrary to the Agency's experience under *Golden,* the Government's argument that denying *res judicata* effect to the July 2011 final order '''would allow registrants to repeatedly litigate the same issues and thus render key portions of 21 CFR 1301.43 meaningless.''' Memorandum and Order, at 9–10 (quoting Gov. Mot. at 3–4). She further reasoned that ''[a]pplicants, like [Respondent,] gain no benefit or tactical advantage by failing to respond to an order to show cause, for during [the] application period they are without the authority to handle controlled substances.'' *Id.* at 10.

Yet, it is within the Agency's experience that registrants, especially those who are the subject of a criminal investigation or pending criminal charges (as well as state administrative proceedings), choose not to contest a Show Cause proceeding. For any number of reasons, a criminal investigation may ultimately result in the prosecutor declining to file charges, and even where charges are filed, a prosecution may result in an acquittal. Moreover, a final disposition may not occur for several years. So, too, it may take several years for a state administrative proceeding to come to a conclusion. During that period, material witnesses may become unavailable, and even where they remain available, their recollections may become faulty; other evidence may be discarded. Yet nothing in the CSA or DEA's regulations prevents a person whose registration has been revoked from reapplying, and this can occur years after the misconduct which was the basis of the first proceeding. *See Robert L. Dougherty,* 76 FR 16823 (2011).

In *Dougherty,* DEA revoked a physician's registration in 1995. *Id.* at 16824–25. More than a decade later, the physician applied for a new registration. *Id.* at 16823. While the physician attempted to relitigate many of the factual findings made in the Agency's 1995 decision and final order, as well as the factual findings made in a 1997 state board proceeding, this Agency held that these findings were *res judicata. See id.* at 16830–16833.

It is true that in *Dougherty,* the findings, which were given preclusive effect, were made in an Order which was issued following a hearing. Yet, had the physician waived his right to a hearing when the Agency initially took action, under *Golden,* the Government would have been required to prove its case—nearly twenty years after the underlying misconduct—through witness testimony and other evidence. This is a ludicrous result.

Thus, while it may be that a former registrant gains no benefit from failing to respond to an Order to Show Cause because he will remain unregistered—a proposition which is not free of dispute—*Golden* nonetheless creates the wrong incentive and wastes scarce Agency resources. Where the Agency has proposed the denial of an application, the applicant should be encouraged to challenge the Agency's

[2] In *Owens,* I rejected the ALJ's reliance, in recommending a sanction, on evidence that the registrant ''ha[d] 561 patients from underserved counties, and [that] many of these patients have limited incomes.'' 74 FR at 36756. In so holding, I noted that section 823(f)'s public interest standard ''is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider'' and that ''consideration of the socioeconomic status of a practitioner's patient population is not mandated by'' the relevant provisions of the Act, ''which focus primarily on the acts committed by a practitioner.'' *Id.* at 36757.

In *Owens,* I further held that such evidence ''has no bearing on whether [a registrant] has accepted responsibility and undertaken adequate corrective measures,'' which are two of the showings which a registrant must make in order to rebut the Government's *prima facie* showing that a registrant has committed acts which render his registration inconsistent with the public interest. *Id.* In addition, I further noted the inherent unworkability of the ALJ's proposed rule, and that it ''would inject a new level of complexity into already complex proceedings and take the Agency far afield of the purpose of the CSA's registration provisions, which is to prevent diversion.'' *Id.* at n.22.

[3] The circumstance described by Respondent does not remotely approach any of the circumstances cited by the Restatement as a ground for invoking this exception, which suggest that it is extremely narrow in its scope. Specifically, the comment gives as examples: where ''one party may conceal from the other information that would materially affect the outcome of the case,'' especially where ''there is a fiduciary relationship between the parties''; where ''one of the parties may have been laboring under a mental or physical disability that impeded effective litigation and that has since been removed''; and where ''the amount in controversy in the first action may have been so small in relation to the amount in controversy in the second that preclusion would be plainly unfair.'' Restatement § 28, cmt. j.

contention when the evidence is freshest. Indeed, litigation when the evidence is freshest enhances the accuracy of the public interest determination and is one of the underlying reasons for the doctrine of issue preclusion.

Moreover, in response to the increase in the diversion of prescription controlled substances, the number of Show Cause Orders issued by the Agency has doubled in recent years. While some of these matters are resolved by the registrants agreeing to surrender their registration, many of them are not and require the issuance of a decision and order, even where the registrant waived his/her right to a hearing. Allowing an applicant to relitigate issues which he/she had a full and fair opportunity to litigate in a prior proceeding but chose not to, mis-allocates the scarce resources of both the Office of Administrative Law Judges and the Office of the Administrator.[4] *Cf. Arizona* v. *California,* 530 U.S. 392, 412 (2000) (doctrine of *res judicata* '''is not based solely on the defendant's interest in avoiding the burdens of twice defending a suit, but is also based on the avoidance of unnecessary judicial waste''' (quoting *United States* v. *Sioux Nation,* 448 U.S. 371, 432 (1980)); *Parklane Hosiery Co., Inc.,* v. *Shore,* 439 U.S. 322, 326 (1979) (''Collateral estoppel, like the related doctrine of *res judicata,* has the dual purpose of protecting litigants from the burden of relitigating an identical issue with the same party . . . and of promoting judicial economy by preventing needless litigation.'').

To be sure, the Restatement of Judgments provides that an issue is not entitled to preclusive effect unless it is actually litigated in the prior proceeding, and that an issue is not actually litigated where a judgment is entered by default or where an issue is ''raised by a material allegation of a party's pleading but is admitted . . . by virtue of a failure to deny [it] in a responsive pleading.'' Restatement § 27, cmt. e. Be that as it may, an increasing number of jurisdictions reject this view and ''allow findings made in default proceedings to collaterally estop, provided that the defaulted party could have appeared and defended if he had wanted to.'' *In re Catt,* 368 F.3d 789, 791 (7th Cir. 2004) (citing Indiana cases). *See also Evans* v. *Ottimo,* 469 F.3d 278, 282 (2d Cir. 2006) (noting that under New York law, '''when a party defaults by failure to answer . . . the defaulting litigant may not further contest the liability issues''') (citation omitted); *In re Cantrell,* 329 F.3d 1119, 1123–24 (9th Cir. 2003); *Gottlieb* v. *Kest,* 141 Cal. App. 4th 110, 149 (Cal. Ct. App. 2006) (''A default judgment conclusively establishes, between the parties so far as subsequent proceedings on a different cause of action are concerned, the truth of all material allegations contained in the complaint in the first action, and every fact necessary to uphold the default judgment.'') (internal quotations and other citations omitted); *In re Dawson,* 338 B.R. 756, 761 (Bankr. N.D. Ohio 2006) (applying collateral estoppel under Ohio law to preclude relitigation of findings made in trial on the merits where party failed to appear at earlier trial); *Matter of Latimore,* 252 A.D.2d 217, 219–20 (N.Y. App. Div. 1999) (collaterally estopping attorney in disciplinary proceeding from relitigating findings made in earlier proceeding in which she defaulted); *TransDulles Center, Inc.,* v. *Sharma,* 472 SE.2d 274, 276 (Va. 1996) (applying collateral estoppel to issues essential to default judgment where ''[t]estimonial and documentary evidence was presented ex parte in the [trial] court hearing''); *Jackson* v. *R.G. Whipple, Inc.,* 627 A.2d 374, 380 (Conn. 1993) (''[H]ad there been a full and fair opportunity to litigate [the] issues and such issues were necessary to a default judgment, that judgment should put to rest subsequent litigation of all issues necessary for the rendering of the default judgment.''), *abrogated on other grounds by Macomber* v. *Travelers Property & Cas. Corp.,* 804 A.2d 180, 195–96 (2002); *Heggy* v. *Grutzner,* 456 NW.2d 845, 849 (Wis. 1990) (precluding relitigation of factual findings essential to default judgment entered in earlier case where party ''intentionally evaded service of process''); *Masciarelli* v. *Maco Supply Corp.,* 224 So.2d 329, 330 (Fla. 1969) (applying collateral estoppel to preclude relitigation of issue, where issue was decided by default judgment in prior litigation, personal service was accomplished, and party failed to answer complaint).

Moreover, giving preclusive effect to findings made in a default proceeding does not violate the Due Process Clause, which requires only ''that the party sought to be precluded have had an opportunity for a hearing.'' *In re Catt,* 368 F.3d at 792. In any event, notwithstanding that Respondent did not request a hearing, the findings of the July 2011 order were not rendered in a classic default proceeding as the Government was required to submit substantial evidence to support its allegations and extensive findings were made based on that evidence.

Accordingly, I conclude that to the extent that *Golden* or any other Agency decision holds that a respondent is entitled to relitigate the factual findings and legal conclusions of an Agency final order because he/she waived his/her right to a hearing in the prior proceeding, it is overruled. Whether the prior agency decision and order was based solely on the evidence submitted by the Government where an applicant waived hearing, or on the basis of a record of a hearing conducted pursuant to 21 CFR 1316.41 *et seq.,* the Agency's factual findings and legal conclusions are entitled to preclusive effect in a subsequent proceeding.

This is not to say that the applicant is foreclosed from putting on any evidence in the subsequent proceeding. That evidence, however, is limited to that which is relevant to, and probative of, '''the critical issue [of] whether the circumstances, which existed at the time of the prior proceeding, have changed sufficiently to support [the] conclusion that' granting the application would be consistent with the public interest.'' *Dougherty,* 76 FR at 16830 (quoting *Stanley Alan Azen,* 61 FR 57893, 57893–94 (1996)). Thus, in the second proceeding, a respondent can put on evidence of acceptance of responsibility as well as remedial measures he has undertaken. What he/she cannot do, however, is relitigate the findings of misconduct made in the earlier Agency decision and order.[5]

In any event, here, as the ALJ found, Respondent asserted that UC1 complained of back pain when both the recording of the visit and the officer's testimony establish otherwise. ALJ 24. Likewise, the ALJ found that Respondent's testimony with respect to UC2 (who credibly testified that she never told Respondent that she had any pain), lacked ''forthrightness'' and ''candor.'' *Id.* at 25. Notwithstanding his evidence that he completed a course on prescribing, Respondent's failure to testify truthfully about his prescribings to the two undercover officers demonstrates that he does not accept responsibility for his misconduct and that the circumstances have not '''changed sufficiently to support [the] conclusion that' granting [his] application would be consistent with

[4] Obviously, if an applicant was not properly served with the Show Cause Order in the prior proceeding, he/she did not have a full and fair opportunity to litigate the issues. Respondent, however, acknowledges that he was served with the first Show Cause Order.

[5] In addition to the 2011 Decision and Order, which denied Respondent's first application, on October 8, 2012, I issued a Decision and Order denying Respondent's second and third applications. *See Jose Gonzalo Zavaleta,* 77 FR 64128, 64131 (2012).

the public interest.'' *Dougherty,* 76 FR at 16883 (quoting *Azen,* 61 FR at 57893–94).

Buttressing this conclusion, the ALJ found that on his December 2010 application, Respondent failed to disclose both the March 2008 voluntary surrender of his registration as well as the suspension of his state controlled substance registration in September 2010. These falsifications were clearly capable of influencing the decision of the Agency and were thus material; the 2008 surrender occurred following an investigation into his prescribing to the undercover officers without a legitimate medical purpose, and the loss of his state controlled substance registration was itself an independent and adequate ground for denying his application. *See Hooper* v. *Holder,* 2012 WL 2020079, *2 (4th Cir. 2012).

Accordingly, I adopt the ALJ's recommended sanction and will order that Respondent's application be denied.

Order

Pursuant to the authority vested in my by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Jose Gonzalo Zavaleta, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective June 10, 2013.

Dated: May 2, 2013.

Michele M. Leonhart,

Administrator.

Frank Mann, Esq., for the Government
Jonathan D. Goins, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACTS, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Gail A. Randall. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. §§ 551 *et. seq.,* to determine whether a physician's application for a DEA certificate of registration should be denied under the Controlled Substances Act, 21 U.S.C. §§ 823(f) (2006).

I. PROCEDURAL BACKGROUND

On September 6, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration issued an Order to Show Cause to Jose G. Zavaleta, M.D., (''Respondent'' or ''Dr. Zavaleta''), seeking to deny his application [1] for a DEA Certificate of Registration as a practitioner under 21 U.S.C. § 823(f), because his registration would be inconsistent with the public interest. [Administrative Law Judge Exhibit (''ALJ Exh.'') 1]. Specifically, the Order to Show Cause alleged that in 2008 the Respondent violated federal law by issuing prescriptions for schedule III and IV controlled substances without a legitimate medical purpose, without establishing a physician-patient relationship, and by acting outside the usual course of professional practice in prescribing controlled substances to undercover agents.[2]

On September 29, 2011, the Respondent filed a timely request for a hearing on the allegations raised by the Order to Show Cause dated September 6, 2011. [ALJ Exh. 2].

The hearing was held in Baton Rouge, Louisiana, on February 28, 2012. [ALJ Exh. 4]. At the hearing, both parties called witnesses to testify and introduced documentary evidence. [Transcript (''Tr.'') Volume I]. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law, and Argument (Govt. Brief and Resp. Brief).

II. ISSUE

The issue in this case is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration (''DEA'' or ''Government'') should deny the application for a DEA Certificate of Registration of Jose G. Zavaleta, M.D., control number W11043099C, as a practitioner, pursuant to 21 U.S.C. § 823(f), because to grant his application would be inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f). [ALJ Exh. 3; Tr. at 6].

III. FINDINGS OF FACT

I find by a preponderance of the evidence, the following facts:

A. The Respondent's Personal and Professional Background

The Respondent has been a physician for twenty-nine years, practicing emergency room medicine for approximately ten of those years. [Tr. 115, 117]. He is sixty years old. [Tr. 115]. He received his medical education at The National University of Trujillo, Peru, completed his education in Frankfurt Hospital in Philadelphia, Pennsylvania, and graduated from a residency at the LSU Medical Center in Shreveport, Louisiana. [Tr. 116]. The Respondent has active medical licenses in Louisiana and Alabama. [Tr. 117, 153, 155–156, 231–232]. He also has a current Louisiana Board of Pharmacy Controlled Dangerous Substance License, which authorizes him to handle controlled substances. [Tr. 154–155; Resp. Exh. 6]. On March 26, 2008, the Respondent voluntarily surrendered his DEA registration. [Tr. 158–160; Govt. Exh. 4].

In August of 2007, the Respondent opened a family practice clinic in Alexandria, Louisiana. [Tr. 117, 119–120]. There, he also treated chronic pain patients. [Tr. 122]. He used small signs to advertise his clinic. [Tr. 76]. At the clinic, Respondent maintained approximately two hundred and forty medical charts.[3] [Resp. Exh. 11]. However, as of the time of this hearing, the Respondent had closed this clinic. [Tr. 170].

To determine if a pain patient is addicted to controlled substances, the Respondent testified that he knows to question the patient and examine the patient, trying to identify the source of the pain. [Tr. 122]. The Respondent also testified that he would ask for prior medical records, which he stated were difficult to obtain. [*Id.*]. The Respondent

[1] In July of 2008, the Respondent filed an application for a DEA certificate of registration, control number W08092985. The DEA issued an Order to Show Cause regarding this application on February 23, 2009. The Respondent failed to respond to that Order to Show Cause, and on July 27, 2011, the DEA Administrator issued a Final Order denying this application. [ALJ Exh. 1]. In April of 2010, the Respondent filed another application, control number W10020882, and in December of 2010, [Govt Exh. 2], the Respondent filed a third application, control number W10078290. On March 2, 2011, the DEA Deputy Assistant Administrator issued an Order to Show Cause proposing to deny these two applications. The Respondent failed to respond to this Order to Show Cause. The record contains no further information concerning these two applications. On July 1, 2011, the Respondent filed application W11043099, and it is this application which is the subject of this proceeding.

[2] The Order to Show Cause asserted that the facts supporting this Order to Show Cause are the same facts contained in the Orders to Show Cause issued February 23, 2009, and March 2, 2011, and the Administrator's Final Order, all of which were attached to this Order to Show Cause and incorporated by reference. For a full discussion of the *res judicata* issue raised by these facts, see the order attached at Appendix A.

[3] The Government challenged the reliability of this hearsay document. I find, based upon the Respondent's testimony concerning the procedure used by his attorney to have this exhibit prepared, that the record has an adequate indicia of reliability to withstand the hearsay objection. [Tr. 219–221]. Within those charts, he prescribed hydrocodone 100 times, or approximately 14.8% of all of his prescriptions issued between July 2007 and March 2008. He issued Xanax 17 times, or 2.5% of his total prescriptions of 674 during this time period. [Resp. Exh. 11]. He also prescribed Phenergan with codeine 82 times, or approximately 12% of his total prescriptions. [Resp. Exh. 11; *see also* Tr. 169–171]. However, I find these statistics have little weight, given DEA precedent on this issue. Specifically, the Agency has revoked ''other practitioners' registrations for committing as few as two acts of diversion.'' *Jayam Krishna-Iyer, M.D,* 74 Fed. Reg. 459, 463 (DEA 2009) (*citing Alan H. Olefsky,* 57 Fed. Reg. 928, 928–29 (DEA 1992)).

also would limit any prescribing of controlled substances to twenty tablets at a time. [Tr. 123]. But the Respondent credibly testified that he found it difficult to identify patients who were addicted to controlled substances, and that he did not often identify such patients in his practice. [Tr. 124]. He testified that he would need to see a patient multiple times to satisfactorily diagnose a drug addiction problem. [*Id.*]. Patients with chronic complaints would be seen every month. [Tr. 125].

The Respondent further testified that he was remorseful regarding the issuance of the prescriptions to the undercover agents. [Tr. 173–174]. He testified that although he ''failed'' when treating the undercover agents, he learned that he had to become ''more vigilant'' when dealing with patients seeking controlled substances. [Tr. 174]. He also testified that he made mistakes with his DEA applications and that he ''should have give(n) [his applications] more careful review.'' [*Id.*]. Dr. Zavaleta acknowledged the severity of his conduct but asserted that he ''learned [his] lesson'' and now has ''basically . . . rehabilitated myself.'' [Tr. 174–175].

B. Treatment of Ricky Harris

On January 23, 2008, Ricky Harris [4] visited Dr. Zavaleta's clinic. [Govt. Exh. 12]. During Dr. Zavaleta's examination of Mr. Harris, he took his blood pressure and temperature. [*Id.*]. He also measured and weighed Mr. Harris. [*Id.*]. Dr. Zavaleta counseled Mr. Harris about his weight and high blood pressure and urged him to lose weight. [*Id.*].

Mr. Harris presented complaints of symptoms from what he claimed was a sexually transmitted infection. [Tr. 14–15; Govt. Exh. 20]. Dr. Zavaleta proceeded to question Mr. Harris about his symptoms. [Govt. Exh. 12]. He inquired about Mr. Harris's sexual history and number of sexual partners. [*Id.*]. Mr. Harris reported that he had experienced these symptoms in the past and that he had been previously treated for a sexually transmitted infection. [*Id.*]. When the Respondent sought to physically examine his genitals, Mr. Harris refused. [Tr. 15, 27, 186]. Likewise, he refused to submit to a blood test to confirm the nature of the infection. [Tr. 186]. He also refused to provide the Respondent with a sample of discharge he reported experiencing. [Tr. 127]. The Respondent agreed to write Mr. Harris a prescription for antibiotics and left the examination room. [Tr. 16, 127–128; Govt. Exh. 12].

Mr. Harris followed Dr. Zavaleta out into the clinic hallway and requested a prescription for Lortab, a pain medication and Schedule III controlled substance. [Tr. 17; Govt. Exh. 20; Govt. Exh. 12]. Dr. Zavaleta initially refused to write Mr. Harris this prescription. [Govt. Exh. 12]. Respondent told Mr. Harris that he could only write a prescription for Lortab if Mr. Harris reported experiencing pain. [*Id.;* Tr. 17]. Mr. Harris testified at the hearing that he did not tell Dr. Zavaleta that he was in pain. [Tr. 15–17, 25, 31–32]. Although the Respondent testified that Mr. Harris complained of shoulder pain and back pain, [Tr. 128–130, 179–180, 182], I find more credible Trooper Horton's testimony as corroborated by the audiovisual recording of the visit and his contemporaneous report. [Govt. Exh. 12; Govt. Exh. 20; *see also* Govt. Exh. 10 (Harris patient file which lacks any mention of shoulder pain); Tr. 182].

Dr. Zavaleta wrote Mr. Harris a prescription for fifteen Lortab tablets. [Tr. 24; Govt. Exh. 10 at 3]. The Respondent wrote ''back pain'' in Mr. Harris' medical chart. [Govt. Exh. 10 at 4–5]. But the Respondent did not perform any examination on Mr. Harris' back other than to listen to his breathing. [Tr. 25–26, 183]. When Mr. Harris requested more Lortabs, the Respondent refused to increase the prescription for a greater number of tablets. [Govt. Exh. 12]. In addition, Mr. Harris sought refills on the prescription, but Dr. Zavaleta refused to authorize any refills. [Tr. 27–28; Govt. Exh. 10; Govt. Exh. 12]. Mr. Harris paid one hundred dollars in cash for that visit. [Tr. 129].

When he testified at the hearing, the Respondent stated that he should have insisted that Mr. Harris provide him a sample of the discharge for testing. [Tr. 132]. He also stated that, given his suspicions, he should have refused to provide a controlled substance prescription to Mr. Harris without prior records or a validating test for pain. [*Id.*]. Respondent further testified that this prescription for hydrocodone issued to Mr. Harris apparently lacked a legitimate medical purpose. [Tr. 188–190].

Although the Respondent stated Mr. Harris made him feel uncomfortable, he provided him with the prescription. [Tr. 131]. Mr. Harris testified that he returned to see the Respondent, but that the Respondent refused to see or treat him. [Tr. 26]. Regarding this second visit, Respondent testified that he instructed his secretary to inform Mr. Harris that he would not provide him with any additional treatment [Tr. 130–131].

C. Treatment of Christy Landry

On January 30, February 8, and February 28, 2008, Respondent treated Christy Landry.[5] [Tr. 37; Govt. Exh. 21]. At the first visit, Ms. Landry told the Respondent that her boyfriend had taken her pills, and that she needed to get a refill of her medication. [Tr. 37]. The Respondent took no action to verify this prior prescription. [Tr. 209].

Ms. Landry told the Respondent that while she did not have any pain, taking hydrocodone made her feel good. [Tr. 38, 67; Govt. Exh. 21].[6] But she told him in response to his questioning that he could describe her symptoms as ''withdrawal symptoms.'' [Tr. 38, 68].[7] The Respondent referred Ms. Landry to a pain clinic. [Govt. Exh. 11 at 7]. However, in follow-up visits, the pain clinic referral was not discussed, and there is no mention in the patient chart that Ms. Landry ever contacted a pain clinic. [Tr. 201–202; Govt. Exh. 11].

At the hearing, the Respondent demonstrated that he examined her heart, checked her back, and examined her abdomen. [Tr. 136–137]. However, Ms. Landry credibly described this examination as the Respondent's effort to search her for a recording device. [Tr. 39–42; Govt. Exh. 21]. Furthermore, he examined her shin and knees, allegedly checking for swelling. [Tr. 40, 137–138].

The Respondent wrote her a prescription for twenty Lorcet, a hydrocodone product and Schedule III controlled substance. [Tr. 43–44, 138; Govt. Exh. 11 at 10]. Ms. Landry requested a prescription for her sister, but the Respondent refused to issue such a prescription. [Tr. 62–63, 70; Govt. Exh. 21 at 1]. Ms. Landry paid one hundred dollars cash for this office visit. [Tr. 45, 139]. She had informed the receptionist that she did not have insurance. [Tr. 45].

Ms. Landry next saw the Respondent on February 8, 2008. [Tr. 46; Govt. Exhs. 11, 21]. He asked her if she had ''generalized pain,'' and Ms. Landry did not respond. [Tr. 47]. However, Ms.

[4] ''Ricky Harris'' is the patient name and alias used by Master Trooper Richard Horton, Louisiana State Police. For consistency with the evidence of record, I will refer to him as Mr. Harris. [*See* Tr. 11–12, 14].

[5] Christy Landry is the patient name used by Detective Heather Owens of the Louisiana State Police. [Tr. 33; Govt. Exh. 11]. For the record, I will use the patient name used by Detective Owens.

[6] Although the Respondent testified that Ms. Landry complained of left shoulder pain, insomnia, and pain in the legs, [Tr. 134, 138], I find her testimony, as corroborated by the contemporaneous police report, more credible. [Tr. 38; Govt. Exh. 21]. The Respondent also acknowledged that such pain complaints were not in Ms. Landry's medical record. [Tr. 193–194; Govt. Exh. 11].

[7] The record contains no evidence that the Respondent is properly registered as a narcotic treatment program participant.

Landry credibly testified that she did not indicate that she had any kind of pain. [Tr. 52]. Rather, Ms. Landry complained of congestion and requested a prescription for cough syrup with codeine. [Tr. 47]. In his physical examination, the Respondent notated that her lungs were ''abnormal'' and that she had a diagnosis of ''chronic cough.'' [Govt. Exh. 11 at 6]. Yet the Respondent could not recall, and did not document, when the cough began in order to verify the chronic nature of the cough. [Tr. 204–205, 226; Govt. Exh. 11]. Further, the Respondent testified that he had not made any medical findings that would substantiate a medical diagnosis of insomnia. [Tr. 210–211]. The Respondent cautioned Ms. Landry on the proper way to take her controlled substance medication. [Tr. 50–51]. She received a prescription for Lorcet and Phenergan,[8] both of which are controlled substances. [Tr. 53; Govt. Exh. 11 at 11]. Ms. Landry paid one hundred dollars in cash for the office visit. [Tr. 52, 62].

Lastly, Ms. Landry visited the Respondent on February 28, 2008. [Tr. 55]. She told him that she wanted a prescription for hydrocodone and Soma. [Tr. 56]. The Respondent refused to issue her a prescription for Soma, but he did issue her a prescription for Xanax,[9] a controlled substance, and Lorcet. [Tr. 55, 60; Govt. Exh. 11 at 12]. At this visit, Ms. Landry did not complain of insomnia or anxiety. [Tr. 60–61]. When asked why she wanted the medication, Ms. Landry laughed and told the Respondent to write whatever he needed to write. [Tr. 56; Govt. Exh. 21 at 5]. As on the other two visits, the Respondent behaved in a flirtatious manner, which Ms. Landry felt was inappropriate. [Tr. 58–59, 68; Govt. Exh. 21]. On the third visit, Ms. Landry admitted that she did not have any pain.[10] [Tr. 139].

At the hearing, the Respondent admitted that he had not prescribed controlled substances to Ms. Landry for legitimate medical reasons. [Tr. 212]. But he also testified that he thought, at the time he wrote the prescriptions, that he was justified in issuing these prescriptions to her. [Tr. 213–214].

[8] Phenergan is a cough syrup containing a combination of promethazine and codeine. It is a schedule V controlled substance. 21 C.F.R. 1308.15(c) (2011).

[9] Xanax is a schedule IV controlled substance. 21 C.F.R. 1308.14(c)(1) (2011).

[10] Although the Respondent testified that he was ''shocked'' when she denied having any pain, I find his testimony lacked credibility, given the tenor of the visit. [Tr. 139–140].

D. Interview of the Respondent

Sergeant Roland Mathews, a Louisiana State Trooper, interviewed the Respondent with the Respondent's attorney present. [Tr. 71, 79; Govt. Exh. 13]. The Respondent told Sgt. Mathews that he could identify drug-seeking patients, and he stated he would not treat such a patient, but that he would help the patient find treatment. [Tr. 81–82; 221–222]. The Respondent also stated that he would need to perform tests and get prior medical records before prescribing such a patient controlled substances. [Tr. 85; 222]. During Sgt. Mathews' investigation, he did not uncover any evidence that the Respondent attempted to obtain prior medical records for Ricky Harris or Christy Landry. [Tr. 86]. Sgt. Mathews testified that Respondent was cooperative in the investigation. [Tr. 90–91].

E. Respondent's Criminal Case

On March 26, 2008, the Respondent was arrested on six counts of prescribing ''controlled substances beyond his respective prescribing authority or for a purpose other than accepted medical treatment of a disease, condition, or illness,'' in violation of LA. REV. STAT. ANN. § 40:971(C)(1). [Govt. Exh. 5]. The Rapides Parish District Attorney's Office offered the Respondent the opportunity to participate in a pretrial intervention program. [Tr. 141]. The pretrial intervention program required that Respondent visit a parole officer monthly for a period of twenty-four months, complete one year of unsupervised probation, pay a seven thousand dollar fine, agree not to seek a DEA registration for two years, notify the Medical Board of his participation in the program, and participate in random drug testing. [Tr. 142; Resp. Exh. 2]. After successfully completing the program in February of 2011, the Respondent had the charges dismissed and the arrest expunged. [Tr. 141–142, 144; Resp. Exhs. 4 and 5].

F. The Medical Board Action and State Controlled Substance License

On June 24, 2010, the Respondent entered into a Consent Order with the Louisiana State Board of Medical Examiners (''Medical Board'') regarding his criminal charges. [Govt. Exh. 9; Resp. Exh. 8]. The Medical Board issued a public reprimand, and placed conditions upon his continued practice of medicine which included: (1) that the Respondent successfully complete the terms and conditions of the pretrial intervention program; (2) that the Respondent take continuing medical education regarding proper prescribing; and (3) that the Respondent pay a one thousand dollar fine to the Medical Board. [Tr. 146; Govt. Exh. 9 at 4]. The Respondent completed these requirements. [Tr. 148]. Currently, the Respondent maintains an active Louisiana medical license. [Tr. 111–112, 153].

Pursuant to the Consent Order with the Medical Board, on June 11–13, 2008, the Respondent took a three-day course at the University of South Florida entitled ''Prescribing Controlled Drugs: Critical Issues and Common Pitfalls of Misprescribing.'' [Resp. Exh. 9]. He credibly testified that the course taught him how to better perform an evaluation of patients seeking controlled substances. [Tr. 150].

By agreement with the Louisiana Board of Pharmacy in September 2010, the Respondent's Louisiana controlled substance license was suspended. [Govt. Exh. 24]. On February 14, 2011, his state controlled substance license was reinstated, and Dr. Zavaleta's license remains current and active, with an expiration date of August 1, 2012. [Govt. Exh. 24; Resp. Exh. 6].

G. Respondent's DEA Application

On July 1, 2011, the Respondent electronically submitted an application for a DEA certificate of registration. [Tr. 95–96; Govt. Exh. 1]. The application was certified, using the Respondent's name. [Tr. 95, 97; Govt. Exh. 1 at 4]. As part of the application for a certificate or registration, the Agency asks four ''liability'' questions. [Tr. 96–97; Govt. Exh. 1 at 3]. DEA Diversion Investigator Cheryl Golden testified that the purpose of these liability questions is to determine if there has been any previous disciplinary action taken against the applicant prior to deciding whether to approve the pending application. [Tr. 98].

On this application, the Respondent answered ''Yes'' to the second question: ''Has the applicant ever surrendered for cause or had a federal controlled substance registration revoked, suspended, restricted or denied?'' [Tr. 97; Govt. Exh. 1 at 3]. The third question asks if the applicant had ''ever surrendered for cause or had a state professional license for a controlled substance registration revoked, suspended, denied, restricted or placed on probation,'' and the Respondent answered ''No,'' to this question. [Tr. 97; Govt. Exh. 1 at 3]. However, on September 2, 2010, the Respondent's Louisiana controlled substances registration had been suspended. [Govt. Exh. 24; *see also* Govt. Exh. 8].

Subsequently, on February 14, 2011, the Respondent's Louisiana controlled substances registration was reinstated. [Tr. 100, 155; Govt. Exh. 24].

On December 8, 2010, the Respondent had also submitted an electronic application for a DEA registration.[11] [Govt. Exh. 2]. On this application, the Respondent answered ''No,'' to all four liability questions, despite having surrendered his DEA registration number BZ5998250, in March of 2008, and the suspension of his Louisiana controlled substance license in September of 2010. [Tr. 104–105; Govt. Exh. 2 at 1; Govt. Exh. 4, 8, and 24]. The Respondent did not participate in a hearing regarding this application. [Tr. 158]. He testified that his incorrect answers to the liability questions on these applications were a mistake. [Tr. 164–167, 215–218].

The Respondent credibly testified that he needs a DEA certificate of registration to obtain hospital privileges and to fully practice medicine. [Tr. 172–173, 175–176]. At the time of the hearing, the Respondent was employed at Outpatient Medical Clinic in Lisbon, Louisiana, and at Rapides Primary Healthcare. [Tr. 176–177].

IV. Statement of Law and Discussion

A. Res Judicata

On November 22, 2011, I issued an order, directing the parties to file briefs, with supporting legal authorities, on whether the doctrine of *res judicata* applies to the Final Order entered against Respondent on July 27, 2011, *see Jose Gonzalo Zavaleta, M.D.,* 76 Fed. Reg. 49,506 (DEA 2011), thus barring Respondent from ''relitigati[ng] the factual findings and conclusions of law of the prior proceeding.'' *Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,830 (DEA 2011). On December 16, 2011, the Government and Respondent filed briefs on this issue. *See* Government's Motion for Partial Summary Disposition and Respondent's Memorandum.

Agency precedent has repeatedly held that factual findings in DEA final orders are entitled to *res judicata. See e.g., Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16,823, 16,830 (DEA 2011); *Stanley Alan Azen, M.D.,* 61 Fed. Reg. 57,893, 57,893–94 (1996). But the Agency has also expressly limited the application of *res judicata,* refusing to apply the principle when the final order was issued without an evidentiary hearing. *Robert M. Golden, M.D.,* 65 Fed. Reg. 5,663, 5,664 (DEA 2000). In this case, the July 27, 2011 Final Order was issued against Dr. Zavaleta solely on the basis of material in the DEA's investigative file and not following an evidentiary hearing. Therefore, I found, consistent with the Agency's holding in *Golden,* that the factual findings and legal conclusions contained in the Final Order were not entitled to *res judicata* effect in this matter.[12]

B. Position of the Parties

1. Government's Position

The Government asserts that the Respondent's application should be denied based upon the Government's preponderating evidence that the Respondent's registration would be contrary to the public interest. [Govt. Brief at 22–23]. Specifically, the Government claims that the Respondent prescribed controlled substances to undercover officers without a legitimate medical purpose and outside the course of professional practice. [Govt. Brief at 15]. Further, the Government argues that by issuing prescriptions to the two undercover officers the Respondent violated state law because he failed to adequately evaluate them, document a proper diagnosis, formulate a legitimate treatment plan, conduct a drug screen for these patients, and maintain adequate medical records. [Govt. Brief at 16–17].

Next, the Government asserts that the Respondent submitted two applications for registration to the DEA that contained materially false information, specifically his responses to the four liability questions. [Govt. Brief at 18–19]. The Government argues that this conduct provides an independent basis to deny Respondent's application. [*Id.*].

Lastly, the Government argues that the Respondent has not articulated any persuasive mitigating factors. [Govt. Brief at 21–22]. The Government claims that the Respondent has never ''acknowledge[d] that he violated Federal or state law or that he assumed complete fault for his actions.'' [Govt. Brief at 21]. Rather, the Government argues that the Respondent testified at the hearing that, given the information he had at the time, he thought he had acted reasonably. [*Id.*]. Given this lack of responsibility and remorse, and the Respondent's failure to testify truthfully about the undercover visits, the Government asserts that Respondent's conduct ''belies any notion that he has accepted responsibility for his actions.'' [Govt. Brief at 22].

2. Respondent's Position

The Respondent argues that his registration is in the public interest and consequently requests that his application be granted. The Respondent notes that he has been punished by the Louisiana Medical Board and the Louisiana Board of Pharmacy for his misconduct in the prescribing of controlled substances to the undercover agents. Although he acknowledges that it is DEA's responsibility to determine the public interest in this matter, he asserts that the DEA should consider these actions when determining the appropriate remedy in this matter. [Resp. Brief at 7].

Next, the Respondent asserts that the Government did not provide an expert witness to testify concerning the legitimacy of the prescriptions written to the undercover officers. [Resp. Brief at 8–9]. He argues that the Government failed to establish that Respondent's physical examination of the undercover officers or Dr. Zavaleta's failure to request medical records for those patients was outside the usual course of professional practice. [Resp. Brief at 10]. The Respondent further argues that the Government has not alleged or proven that the Respondent's conduct was outright drug dealing. [Resp. Brief at 11]. On this point, the Respondent highlights that, although Detective Owens requested a prescription for her sister, the Respondent refused her request. [*Id.*]. Furthermore, the Respondent notes that Dr. Zavaleta has not been convicted of any offenses under federal or state law relating to his handling of controlled substances. [*Id.*].

While Respondent acknowledged that he should not have prescribed controlled substances to the undercover agents, he asserts that he offered substantial mitigating evidence ''to show he would not engage in the same conduct'' in the future. [Resp. Brief at 12]. To this point, the Respondent notes that Dr. Zavaleta completed a three-day continuing medical education course in prescribing controlled substances. [*Id.*]. The Respondent also points out that Dr. Zavaleta cooperated with all agencies involved in this matter, and that he admitted that he made a mistake in prescribing to the undercover officers. [*Id.*]. The Respondent claims he demonstrated remorse for his conduct. [*Id.*]. He admitted he had failed and that he had learned his lesson when it came to prescribing controlled substances. [Resp. Brief at 13].

As for material falsification, the Respondent acknowledges that he had failed to answer the liability questions correctly on his two applications for

[11] Although the record copy of Government Exhibit 2 is not a certified copy, DI Golden credibly testified that she confirmed that a certified copy of the registration was on file at DEA. [Tr. 104].

[12] I have attached the relevant order and the parties' briefs as appendix A & B for the Deputy Administrator's consideration.

registration. But, the Respondent argues that his error on these applications was unintentional, because he had ''no reason to hide the information.'' [*Id.*]. However, he concedes that ''[n]o matter how unintentional, his failure [to correctly answer the liability questions] could have the tendency to affect the outcome of his application thereby being materially false.'' [*Id.*].

In conclusion, the Respondent argues that granting his application would be consistent with the public interest. [Resp. Brief at 13–14]. Although the Respondent engaged in misconduct, he asserts that he ''has done everything within his control to make sure this does not happen again.'' [Resp. Brief at 14]. The Respondent ''believes he has demonstrated to this Court that he is remorseful for his actions and will not repeat the same behavior.'' [*Id.*]. Therefore, he requests that his application be approved. [*Id.*].

C. Statement of Law

Section 823(f) of the Controlled Substances Act (''CSA'' or ''the Act'') provides that ''[t]he Attorney General [13] may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the Act requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. § 823(f).

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15,227, 15,230 (DEA 2003). The Deputy Administrator may rely on any one or a combination of factors, and may give each factor the weight he deems appropriate in determining whether an application for a registration should be denied. *Id.* Moreover, the Deputy Administrator is ''not required to make findings as to all of the factors.'' *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall v. DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

The Government bears the burden of proving that the requirements for registration are not satisfied. 21 C.F.R. § 1301.44(d) (2011). The burden of proof shifts to the Respondent once the Government has made its *prima facie* case. *Medicine Shoppe—Jonesborough,* 73 Fed. Reg. 364, 380 (DEA 2008). The Agency has recognized that ''past performance is the best predictor of future performance.'' *ALRA Labs, Inc. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995). Further, the Agency has repeatedly held that ''where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for (his) actions and demonstrate that (he) will not engage in future misconduct.'' *Medicine Shoppe,* 73 Fed. Reg. at 387; *see also Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23,848, 23,853 (DEA 2007). In short, after the Government makes its *prima facie* case, the Respondent must prove by a preponderance of the evidence that he can be entrusted with the authority that a registration provides by demonstrating that he accepts responsibility for his misconduct and that the misconduct will not re-occur.

Under Section 824(a)(1), a registration may also be revoked or suspended ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. § 824(a)(1) (2006). Under Agency precedent, the various grounds for revocation or suspension of an existing registration that Congress enumerated in 21 U.S.C. § 824(a), are also properly considered in deciding whether to grant or deny an application under section 823. *See Anthony D. Funches,* 64 Fed. Reg. 14,267, 14,268 (DEA 1999); *Alan R. Schankman, M.D.,* 63 Fed. Reg. 45,260, 45,260 (DEA 1998); *Kuen H. Chen, M.D.,* 58 Fed. Reg. 65,401, 65,402 (DEA 1993).

Although the Government did not assert material falsification in the Order to Show Cause, the Government did place the Respondent properly on notice of this allegation in the Government's Supplemental Prehearing Statement. Thus, the allegation that the Respondent materially falsified his application is properly considered in this proceeding. *George Mathew, M.D.,* 75 Fed. Reg. 66,138, 66,146 (DEA 2010) (''[T]he failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.''); *CBS Wholesale Distributors,* 74 Fed. Reg. 36,746, 36,750 (DEA 2009). Longstanding Agency precedent has held that the scope of a DEA administrative hearing is determined not only by the allegations contained in the OSC, but also by the parties' prehearing statements. *Darrell Risner, D.M.D.,* 61 Fed. Reg. 728, 730 (DEA 1996); *John Stanford Noell, M.D.,* 59 Fed. Reg. 47,359, 47,361 (DEA 1994).

1. The Material Falsification Allegation

A false statement is material if it ''has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.'' *Kungys v. United States,* 485 U.S. 759, 770 (1988). While the evidence must be ''clear, unequivocal, and convincing,'' the ultimate finding of materiality ''turns on a substantive interpretation of the law.'' *Id.* at 772; *see also Craig H. Bammer, D.O.,* 73 Fed. Reg. 34,327, 34,328 (DEA 2008). However, '[i]t makes no difference that a specific falsification did not exert influence so long as it had the *capacity to do so.'''* *United States v. Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985).

The record raises the issue of whether the Respondent's failure to correctly answer the liability questions on his most recent application and his application in December of 2010 resulted in a material falsification of those applications. DEA has previously held that ''[t]he provision of truthful information on applications is absolutely essential to effectuating [the] statutory purpose'' of determining whether the granting of an application is consistent with the public interest. *Peter H. Ahles, M.D.,* 71 Fed. Reg. 50,097, 50,098 (DEA 2006). In the July 2011 application, the Respondent disclosed his voluntary surrender of his DEA registration. However, he failed to disclose the suspension of his Louisiana controlled substance license, which occurred in September of 2010. Clearly, the Respondent knew or should have known about this suspension by July of 2011. Likewise, in the December 2010 application, the Respondent failed to disclose his voluntary surrender of his DEA registration in March of 2008, or the suspension of his Louisiana controlled substance license in September of 2010.

I find these omissions resulted in the material falsification of the Respondent's applications. Clearly, this information was capable of influencing the decisionmaker in this matter. Respondent's lack of full disclosure in these applications weighs heavily in favor of denying his application for a certificate of registration. *See Shannon L. Gallentine, D.P.M.,* 76 Fed. Reg. 45,864, 45,866 (DEA 2011).

[13] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2011).

2. Factor One: Recommendation of the Appropriate State Licensing Board

While the Medical Board's recommendation is probative, ''DEA maintains a separate oversight responsibility with respect to the handling of controlled substances and has a statutory obligation to make its independent determination as to whether the granting of [a registration] would be in the public interest.'' *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 8,209, 8,210 (DEA 1990); *see also Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 461 (DEA 2009). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 Fed. Reg. 6,580, 6,590 (DEA 2007), *aff'd,* 533 F.3d 828 (DC Cir. 2008). Although not dispositive, state board decisions are relevant on the issue of granting or denying a DEA application. *Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 36,751, 36,755 (DEA 2009); *Martha Hernandez, M.D.,* 62 Fed. Reg. 61,145, 61,147 (DEA 1997).

Here, the Medical Board has not made a direct recommendation concerning the Respondent's DEA application. However, on June 24, 2010, the Respondent entered into a Consent Order with the Louisiana Medical Board. Although not admitting to any misconduct, the Respondent agreed to the Medical Board's action and conditions placed upon his medical license. Specifically, the Medical Board issued a public reprimand, and, among other conditions, required the Respondent to take a continuing medical education course regarding proper prescribing. The Respondent completed all of the requirements levied by the Medical Board, and he currently has an unrestricted, active medical license. Therefore, I find that this factor does not weigh in favor or against Respondent's application for a DEA certificate of registration.

3. Factors Two and Four: The Applicant's Experience With Controlled Substances and Compliance With Applicable State, Federal, or Local Laws Relating To Controlled Substances.

DEA regulation dictates that a prescription, to be valid, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 C.F.R. § 1306.04(a) (2011); *see also* LA. REV. STAT. ANN. § 40:1238.2 (2011).[14] As the Supreme Court explained, ''the prescription requirement. . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006) (citing *United States v. Moore,* 423 U.S. 122, 135 (1975)). Further, a valid prescription under Louisiana law is defined as a ''a written request for a drug. . . issued by a licensed physician. . . for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.'' LA. REV. STAT. ANN. § 40:961(33) (2011).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act ''in the usual course of. . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Laurence T. McKinney, M.D.,* 73 Fed. Reg. 43,260, 43,265 (DEA 2008); *see also Moore,* 423 U.S. 142–43 (noting that evidence established that physician ''exceeded the bounds of ''professional practice,'' when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against. . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. *Kamir Garces-Mejias, M.D.,* 72 Fed. Reg. 54,931, 54,935 (DEA 2007); *United Prescription Services, Inc.,* 72 Fed. Reg. 50,397, 50,407–08 (DEA 2007).

Here, Louisiana law provides that it is unlawful for a physician to ''assist a patient. . . in obtaining a controlled dangerous substance through misrepresentation, fraud, forgery, deception, or subterfuge.'' LA. REV. STAT. ANN. § 40:971.2(B)(1) (2011). By coaching Mr. Harris and Ms. Landry to state they were in pain, and by falsely documenting their medical records to record these pain complaints when neither patient expressed that they were in pain is a violation of this provision.

Louisiana law pertaining to the treatment of chronic pain requires a physician to evaluate the patient to include an ''assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of co-existing illnesses, diseases, or conditions, and an appropriate physical examination.'' LA. ADMIN. CODE tit. 46, § 6921(A)(1) (2011). Here, the Respondent failed to meet this standard, for he did not perform a physical or psychological functions analysis, did not review previous diagnostic studies, previously utilized therapies, or conduct an appropriate physical examination of either Mr. Harris or Ms. Landry. *See Armstrong v. La. State Bd. Of Med. Examiners,* 868 So. 2d 830, 840 (La. Ct. App. 2004) (noting that when a physician prescribes controlled substances for the relief of non-malignant pain ''unaccompanied by appropriate testing, diagnosis, oversight and monitoring. . . the physician falls below generally accepted standards of care''). Although the Respondent looked at the patients' backs, such observation may not be an adequate physical examination. *Jack A. Danton, D.O.,* 76 Fed. Reg. 60,900, 60,910 (DEA 2011) (noting without deciding that mere observation may not be an adequate physical examination).

Further, the Respondent failed to develop an individualized treatment plan for Mr. Harris and Ms. Landry. Louisiana law requires a physician to develop such a plan and to document the plan in the patient's medical records. The plan is to include ''medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's non-cancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.'' LA. ADMIN. CODE tit. 46, § 6921(A)(3) (2011). The medical records here failed to reveal such an individualized treatment plan. Especially lacking in these medical records were any indications that alternative treatments were attempted prior to issuing prescriptions for controlled substances. LA. ADMIN. CODE tit. 46, § 6921(B)(6)(2011).

In the case of Ms. Landry and her multiple visits to Dr. Zavaleta's clinic, the Respondent failed to assess the efficacy of her treatment. Louisiana law requires a physician to ''assure that controlled substance therapy remains

[14] This statutory provision provides in relevant part: A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs * * * Any person who knows or should know that he or she is filling such a prescription * * * to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section. LA. REV. STAT. ANN. § 40:1238.2(A) (2011).

indicated, and evaluate the patient's progress toward treatment objectives.'' LA. ADMIN. CODE tit. 46, § 6921(B)(1). Ms. Landry's chart failed to disclose any treatment objectives, and thus, her progress towards meeting those objectives was also lacking.

Louisiana law also requires a physician to ''document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.'' *Id.* at (B)(5). The Respondent violated this provision when he added Xanax to Ms. Landry's prescriptions without documenting the medical necessity for this anti-anxiety medication.

Lastly, Louisiana case law establishes that it is a violation of the legitimate medical purpose provision when a physician provides a patient with controlled substances based upon their request for the drug. *See Louisiana v. Moody,* 393 So. 2d 1212, 1215 (La. 1981). Both Mr. Harris and Ms. Landry specifically requested hydrocodone products, and the Respondent provided them with a prescription for this requested controlled substance. Further, given the statements by both Mr. Harris and Ms. Landry that they were not experiencing any pain, the Respondent violated this provision when he prescribed Lorcet or Lortab for their non-existent pain.

Accordingly, I find that the Government has made a *prima facie* case regarding the failure of the Respondent to prescribe controlled substances for a legitimate medical purpose in the usual course of professional practice.[15]

4. Respondent's Remorse and Corrective Action

The critical consideration in this proceeding is whether the circumstances, which existed at the time of the surrender of his registration in 2008, have changed sufficiently to support a conclusion that Respondent's registration would be in the public interest. *Ellis Turk, M.D.,* 62 Fed. Reg. 19,603, 19,604 (DEA 1997). As this Agency has repeatedly held, a proceeding under the Act ''is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused. . . their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility carried by such a registration.'' *Jon Karl Dively, D.D.S.,* 72 Fed. Reg. 74,332, 74,334 (DEA 2007).

At the hearing, the Respondent acknowledged that he should have refused to provide Mr. Harris with the Lortab prescription he requested without prior records or validating tests. He credibly testified that he agreed that providing Mr. Harris with a prescription for hydrocodone was not for a legitimate medical purpose. Nevertheless, I remain concerned about the Respondent's insistence at the hearing that Mr. Harris had told him that he had back pain. My review of the undercover recording does not substantiate his assertion, and Mr. Harris credibly testified that he had not told the Respondent that he had any pain. To his credit, however, when Mr. Harris returned to his office, the Respondent refused to treat him.

Likewise, at the hearing the Respondent admitted that he had not prescribed controlled substances to Ms. Landry for a legitimate medical purpose. Although Ms. Landry asserted that she needed a refill of her controlled substance prescription, the Respondent took no action to verify that her original controlled substance prescription had been provided for a legitimate medical purpose. To his credit, at the first visit Ms. Landry had requested a prescription for her sister, and the Respondent refused to provide her with such a prescription. But despite Ms. Landry's credible testimony denying that she had told the Respondent that she had any type of pain, the Respondent testified that he thought, at the time he wrote the prescriptions, that he was right in his prescribing to her. The Respondent's lack of forthrightness is troubling.

Lastly, the Respondent was cooperative with the investigators. He also took remedial training in the handling of controlled substances, and he credibly testified that he is more knowledgeable about drug-seeking behavior.

V. Conclusion and Recommendation

In balance, however, I find that the Respondent's current lack of candor, his material falsification of his DEA applications, and his illegal prescribing of controlled substances in 2008 outweigh his assertions that he can now responsibly handle controlled substance prescriptions. Accordingly, I recommend that the Respondent's current application be denied. Should the Respondent file an application wherein he fully discloses the surrender of his DEA registration for cause and the suspension of his Louisiana controlled substance license, then such candor may be favorably considered.

Dated: May 10, 2012.

Gail A. Randall,

Administrative Law Judge.

[FR Doc. 2013–11185 Filed 5–9–13; 8:45 am]

BILLING CODE 4410–09–P

[15] Given the overwhelming evidence of the Respondent's failure to issue controlled substances for a legitimate medical purpose, I do not address the Government's allegations that the Respondent's flirtatious behavior with Ms. Landry was outside the usual course of professional practice.

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1622]

NIJ Evaluation of Hand-Held Cell Phone Detector Devices

AGENCY: National Institute of Justice, Department of Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) is soliciting interest in supplying hand-held cell phone detector devices for participation in an evaluation by the NIJ Corrections Technology Center of Excellence (CXCoE).

SUPPLEMENTARY INFORMATION: NIJ is soliciting interest in supplying hand-held cell phone detector devices for participation in an evaluation by the NIJ Corrections Technology Center of Excellence (CXCoE). The evaluation is focused on field operation in correctional facility scenarios. Supplied hand-held cell phone detectors must:

- Weigh less than 8 lbs,
- Be battery operated with a minimum run time of 2 hours,
- Be designed for single person operation, and
- Operate using Radio Frequency (RF) and/or Non-Linear Junction Detection (NLJD) technology

Manufacturers interested in participating in this evaluation will be asked to execute a Letter of Understanding. Participating manufacturers will receive a copy of the CXCoE Test & Evaluation Plan. Interested parties are invited to contact NIJ for information regarding participation, Letters of Understanding, and shipping. Letters of Understanding may be obtained from and should be submitted to Jack flame, National Institute of Justice, Office of Science and Technology, 810 7th Street NW., Washington, DC 20531, emailed to *jack.harne@usdoj.gov,* or faxed to (202) 305–9907.

DATES: Manufacturers who wish to participate in the program must submit a request and an executed Letter of Understanding by 5 p.m. Eastern Time

on June 24, 2013. Supplied devices are to be loaned to the CXCoE for a period of time no less than 90 days and must be received by the CXCoE by July 1, 2013.

FOR FURTHER INFORMATION CONTACT: Jack Harne, by telephone at (202) 616–2911 [**Note:** this is not a toll-free telephone number], or by email at *jack.harne@usdoj.gov.*

Greg Ridgeway,

Acting Director, Deputy Director, National Institute of Justice.

[FR Doc. 2013–11049 Filed 5–9–13; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Coal Mine Dust Sampling Devices; Correction

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice; correction.

SUMMARY: On April 30, 2013, Mine Safety and Health Administration (MSHA) published a notice in the **Federal Register**, docket number [MSHA–2013–0008], announcing the proposed extension of a currently approved information collection involving Continuous Personal Dust Monitors (CPDMs). In the **ADDRESSES** section of the notice MSHA incorrectly listed the OMB number as 1219–0001. This notice corrects that error and clarifies that comments concerning the information collection requirements of this notice must be clearly identified with ''OMB 1219–0147'' and sent to the MSHA.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Deputy Director, Office of Standards, Regulations, and Variances, MSHA, at *McConnell.Sheila.A@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

Authority: 44 U.S.C. 3506(c)(2)(A).

Dated: May 6th, 2013.

George F. Triebsch,

Certifying Officer.

[FR Doc. 2013–11129 Filed 5–9–13; 8:45 am]

BILLING CODE 4510–43–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS), Meeting of the ACRS Subcommittee on Plant License Renewal; Notice of Meeting

The ACRS Subcommittee on Plant License Renewal will hold a meeting on May 22, 2013, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, May 22, 2013—1:30 p.m. Until 5:00 p.m.

The Subcommittee will review and discuss the license renewal application and the associated draft Safety Evaluation (SER) with open items for the Callaway Plant, Unit 1. The Subcommittee will hear presentations by and hold discussions with the NRC staff, Ameren Missouri, 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), Kent Howard (Telephone 301–415–2989 or Email: *Kent.Howard@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 18, 2012, (77 FR 64146–64147).

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, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 6, 2013.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–11170 Filed 5–9–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Fukushima; Notice of Meeting

The ACRS Subcommittee on Fukushima will hold a meeting on May 23, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, May 23, 2013—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review and discuss the development of a notation vote paper with possible options for addressing the Near Term Task Force (NTTF) Recommendation 1: Enhanced Regulatory Framework. The Subcommittee will hear presentations by and hold discussions with the NRC staff, the Nuclear Energy Institute, 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), Hossein Nourbakhsh (Telephone 301–415–5622 or Email: *Hossein.Nourbakhsh@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 18, 2012, (77 FR 64146–64147).

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, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 6, 2013.

Cayetano Santos,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–11162 Filed 5–9–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Digital I&C; Notice of Meeting

The ACRS Subcommittee on Digital I&C will hold a meeting on May 21, 2013, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, May 21, 2013–8:30 a.m. until 5:00 p.m.

The Subcommittee will review and discuss the following six (6) regulatory guides regarding the use of digital computer software in safety systems of nuclear power plants:

1. Proposed Revision 1 to Regulatory Guide 1.169 (DG–1206), ''Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants;''
2. Proposed Revision 1 to Regulatory Guide 1.170 (DG–1207), ''Test Documentation for Digital Computer Software Used in Safety Systems of Nuclear Power Plants;''
3. Proposed Revision 1 to Regulatory Guide 1.171 (DG–1208), ''Software Unit Testing for Digital Computer Software Used in Safety Systems of Nuclear Power Plants;''
4. Proposed Revision 1 to Regulatory Guide 1.172 (DG–1209), ''Software Requirement Specifications for Digital Computer Software and Computer Electronics Used in Safety Systems of Nuclear Power Plants;''
5. Proposed Revision 1 to Regulatory Guide 1.173 (DG–1210), ''Developing Software Life-Cycle Processes for Digital Computer Software Used in Safety Systems of Nuclear Power Plants;'' and,
6. Proposed Revision 2 to Regulatory Guide 1.168 (DG–1267), ''Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants.''

The Subcommittee will hear presentations by and hold discussions with 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), Christina Antonescu (Telephone 301–415–6792 or Email: *Christina.Antonescu@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 18, 2012, (77 FR 64146–64147).

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, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 2, 2013.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–11166 Filed 5–9–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Reliability & PRA; Notice of Meeting

The ACRS Subcommittee on Reliability & PRA will hold a meeting on May 22, 2013, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, May 22, 2013—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review and discuss the progress of the Level 3 Probabilistic Risk Assessment (PRA) development plan. The Subcommittee will hear presentations by and hold discussions with 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), John Lai (Telephone 301–415–5197 or Email: *John.Lai@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 18, 2012, (77 FR 64146–64147).

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, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 2, 2013.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–11167 Filed 5–9–13; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Sunshine Act Meeting: Board of Governors Board Votes To Close April 24, 2013, Meeting

By telephone vote on April 24, 2013, members of the Board of Governors of the United States Postal Service met and voted unanimously to close to public observation its meeting held in Washington, DC, via teleconference. The Board determined that no earlier public notice was possible.

MATTERS CONSIDERED

1. Strategic Issues.
2. Legislative Issues.

GENERAL COUNSEL CERTIFICATION

The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION

Requests for information about the meeting should be addressed to the Secretary of the Board, Julie S. Moore, at (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2013–11216 Filed 5–8–13; 11:15 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30507; 812–13915]

Forum Investment Advisors, LLC, *et al.;* Notice of Application

May 6, 2013.

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 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 12(d)(1)(B) of the Act.

Applicants: Forum Investment Advisors, LLC (''FIA''), Forum ETF Trust (the ''Trust''), and Foreside Fund Services, LLC (collectively, ''Applicants'').

SUMMARY: *Summary of Application:* Applicants request an order that permits: (a) Series of certain actively managed 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 negotiated market prices; (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; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares.

DATES: *Filing Dates:* The application was filed on June 27, 2011, and amended on December 12, 2011, October 29, 2012 and April 1, 2013. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

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 June 3, 2013, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, 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: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Forum Investment Advisors, LLC and Forum ETF Trust, Three Canal Plaza, Suite 600, Portland, ME 04101 and Foreside Fund Services, LLC, Three Canal Plaza, Suite 100, Portland, ME 04101.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551–6990 or Jennifer L. Sawin, Branch Chief, at (202) 551–6821 (Division of Investment Management, Exemptive Applications 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 an applicant using the Company name box, at *http://*

www.sec.gov/search/search.htm or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is registered as an open-end management investment company under the Act and is a statutory trust organized under the laws of Delaware. The Trust will create and operate an actively managed investment series of the Trust (''Initial Fund'') that will offer Shares.[1] The investment objective of the Initial Fund will be to seek to profit from a rise in hard currencies relative to the U.S. dollar. The Initial Fund will seek to achieve its investment objective by investing at least 80% of the value of its net assets (plus borrowing for investment purposes) in ''hard currency'' denominated investments and gold.

2. Applicants request that the order apply to the Initial Fund and any future series of the Trust or of other open-end management companies that may utilize active management investment strategies (''Future Funds''). Any Future Fund will (a) be advised by FIA or an entity controlling, controlled by, or under common control with FIA (FIA and each such other entity and any successor thereto included in the term ''Investment Manager'') [2], and (b) comply with the terms and conditions of the application.[3] The Initial Fund and Future Funds together are the ''Funds''. Each Fund will operate as an actively managed exchange-traded fund (''ETF''). Each Fund will consist of a portfolio of securities (including fixed income securities and/or equity securities) and/or currencies, other assets and other positions including short sales and other short positions (''Short Positions'') traded in the U.S. and/or non-U.S. markets (''Portfolio Instruments''). To the extent consistent with other investment limitations, the Funds may invest all of their assets in mortgage- or asset-backed securities, including ''to-be-announced transactions'' or ''TBA Transactions'',[4] and may engage in forward commitment transactions [5], forward foreign currency contracts, options contracts, futures contracts or swap agreements.[6] Funds may also invest in ''Depositary Receipts''.[7] A Fund will not invest in any Depositary Receipts that the Investment Advisor (as defined below) deems to be illiquid or for which pricing information is not readily available. The Future Funds might include one or more ETFs that invest in other open-end and/or closed-end investment companies and/or ETFs.[8]

3. An Investment Manager will be an investment adviser to the Initial Fund and each of the other Funds. On February 28, 2013, FIA, a Delaware limited liability company, filed a Form ADV with the Commission to register as an ''investment adviser'' under section 203 of the Investment Advisers Act of 1940 (''Advisers Act''). Subject to the oversight and authority of the board of trustees of the Trust (''Board''), [9] an Investment Manager will develop the overall investment program for each Fund, which includes working with the Investment Advisors to define principal investment strategies (the Investment Advisors, and not the Investment Manager, will make investment decisions with respect to assets of each Fund allocated by the Investment Manager to that Investment Advisor, subject to supervision and oversight by the Investment Manager of each Investment Advisor). The Trust may retain one or more investment advisers (''Investment Advisors'') with respect to the Funds to manage specific strategies suited to the Investment Advisors' expertise, including having multiple Investment Advisors managing portions of a single Fund.[10] Each Investment Advisor will be registered under the Advisers Act.[11] A registered broker-dealer under the Securities Exchange Act of 1934, as amended (''Exchange Act''), which may be an affiliate of the Investment Manager or any Investment Advisor, will be selected and approved by the Board to act as the distributor and principal underwriter of the Funds (''Distributor''). Foreside Fund Services LLC will serve as the initial Distributor of Shares and Applicants request that the requested order apply to any future Distributor of Shares. Foreside is not affiliated with FIA.

4. Applicants anticipate that a Creation Unit will consist of at least 50,000 Shares and that the price of a Share will range from $20 to $200. All orders to purchase Creation Units must be placed with the Distributor by or through a party (''Authorized Participant'') that has entered into a participant agreement with the Distributor with respect to the creation and redemption of Creation Units. An Authorized Participant is either: (a) A broker or dealer registered under the Exchange Act (''Broker'') or other participant in the Continuous Net Settlement System of the National Securities Clearing Corporation (''NSCC''), a clearing agency registered with the Commission and affiliated with the Depository Trust Company (''DTC''); or (b) a participant in the DTC (such participant, ''DTC Participant''). The Initial Fund and certain Future Funds will generally be purchased entirely for cash and will be redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will be entirely in cash or include cash under limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of

[1] The Initial Fund is expected to be called the Merk Hard Currency ETF.

[2] For the purposes of the requested order, a ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[3] All entities that currently intend to rely on the order are named as Applicants. Any entity that relies on the order in the future will comply with the terms and conditions of this application. An Investing Fund (as defined below) may rely on the order only to invest in Funds and not in any other registered investment company.

[4] A TBA Transaction is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to the settlement date.

[5] In a forward commitment transaction, the buyer/seller enters into a contract to purchase/sell, for example, specific securities for a fixed price at a future date beyond normal settlement time.

[6] If a Fund invests in derivatives: (a) the Board periodically will review and approve (i) the Fund's use of derivatives and (ii) how the Fund's Investment Advisor assesses and manages risk with respect to the Fund's use of derivatives; and (b) the Fund's disclosure of its use of derivatives in its offering documents and periodic reports will be consistent with relevant Commission and staff guidance.

[7] Depositary Receipts are typically issued by a financial institution, a ''depositary'', and evidence ownership in a security or pool of securities that have been deposited with the depositary. No affiliated persons of Applicants, nor of any Investment Manager, any Investment Advisor, or the Funds, will serve as the depositary bank for any Depositary Receipts held by a Fund.

[8] In no case, however, will such a Fund rely on the exemption from section 12(d)(1) being requested in this application.

[9] The term ''Board'' includes any board of directors or trustees of a Future Fund, if different.

[10] No Fund will utilize investment sub-advisers.

[11] The Investment Manager will be responsible for each Investment Advisor's compliance, in addition to its own compliance, with the terms and conditions set forth in the application, including any such terms and conditions that may relate to the investment activity of an Investment Advisor. Before a Fund enters into an advisory contract with an Investment Advisor, the Investment Manager and the Investment Advisor will execute a compliance agreement (''Compliance Agreement''). Any advisory contract between a Fund and an Investment Advisor will include provisions that obligate the Investment Advisor to comply with the terms and conditions of the order and empower the Investment Manager to terminate the advisory contract if there is a material breach of the terms and conditions of the order by the Investment Advisor.

specified instruments (''Redemption Instruments'') in each case accompanied by a deposit (or refund) of a specified Balancing Amount (as defined below).[12] On any given Business Day [13] the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, and these instruments may be referred to, in the case of either a purchase or a redemption, as the ''Creation Basket''. In addition, the Creation Basket will correspond pro rata to the positions in the Fund's portfolio (including cash positions),[14] except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots; [15] or (c) TBA Transactions, Short Positions [16] and other positions that cannot be transferred in kind [17] will be excluded from the Creation Basket.[18] If there is a difference between the net asset value attributable to a Creation Unit and the aggregate market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Balancing Amount'').

5. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Balancing Amount, as described above; (b) if, on a given Business Day, the Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, the Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash; [19] (d) if, on a given Business Day, the Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because; (i) such instruments are not eligible for transfer through either the NSCC Process or DTC Process; or (ii) in the case of Funds holding non-U.S. investments (''Global Funds''), such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if the Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Global Fund would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[20]

6. Each Business Day, before the open of trading on a national securities exchange as defined in section 2(a)(26) of the Act (''Stock Exchange''), on which the Shares are listed, the Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Creation Basket, as well as the estimated Balancing Amount (if any) for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following Business Day, and there will be no intra-day changes to the Creation Basket except to correct errors in the published Creation Basket. The Stock Exchange will disseminate every 15 seconds throughout the trading day through the facilities of the Consolidated Tape Association an amount representing, on a per Share basis, the sum of the current value of the Portfolio Instruments that were publicly disclosed prior to the commencement of trading in Shares on the Stock Exchange.

7. An investor purchasing or redeeming a Creation Unit from a Fund may be charged a fee (''Transaction Fee'') to protect existing shareholders of the Funds from the dilutive costs associated with the purchase and redemption of Creation Units.[21] All orders to purchase Creation Units must be placed with the Distributor by or through an Authorized Participant and the Distributor will transmit all purchase orders to the relevant Fund. The Distributor will be responsible for delivering a prospectus (''Prospectus'') to those persons purchasing Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it.

8. Shares will be listed and traded at negotiated prices on a Stock Exchange and traded in the secondary market. Applicants expect that the Stock Exchange will select, designate or appoint one or more specialists (''Specialists'') or market makers (''Market Makers'') for the Shares. The price of Shares will be based on a current bid/offer in the secondary market. Transactions involving the purchases and sales of Shares on the Stock Exchange will be subject to customary brokerage fees and charges.

9. Applicants expect that purchasers of Creation Units will include arbitrageurs. Applicants expect that arbitrage opportunities created by the ability to continually purchase or redeem Creation Units at their net asset value per individual Share (''NAV'') should ensure that the Shares will not

[12] The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act of 1933 (''Securities Act''). In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to rule 144A under the Securities Act, the Funds will comply with the conditions of Rule 144A.

[13] ''Business Day'' is defined to include any day that the Fund is open for business, including as required by section 22(e) of the Act.

[14] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV (as defined below) for that Business Day.

[15] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[16] To the extent required by section 18(f) of the Act, Portfolio Instruments and/or cash held in a Fund's portfolio will be segregated to cover Short Positions in such portfolio. *See,* Securities Trading Practices of Registered Investment Companies, Investment Company Act Rel. No. 10666 (Apr. 18, 1979).

[17] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[18] Because these instruments will be excluded from the Creation Basket, their value will be reflected in the determination of the Balancing Amount (defined below).

[19] Applicants state that in determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit which would accrue to the Fund and its investors. Purchases of Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax considerations may warrant in-kind redemptions.

[20] A ''custom order'' is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

[21] Where a Fund permits an in-kind purchaser or redeemer to deposit or receive cash in lieu of one or more Deposit or Redemption Instruments, the purchaser or redeemer may be assessed a higher Transaction Fee to offset the transaction cost to the Fund of buying or selling those particular Deposit or Redemption Instruments.

trade at a material discount or premium in relation to their NAV. Applicants also expect that Specialists or Market Makers, acting in their unique role to provide a fair and orderly secondary market for Shares, also may purchase Creation Units for use in their own market making activities.[22] Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[23]

10. Neither the Trust nor any Fund will be marketed or otherwise held out as a ''mutual fund''. Instead, each Fund will be marketed as an ''actively managed exchange-traded fund.'' Any advertising material where features of obtaining, buying or selling Creation Units are described or where there is reference to redeemability will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire Shares from a Fund and tender those Shares for redemption to a Fund in Creation Units only.

11. Each Fund's Web site, which will be publicly available prior to the public offering of Shares, will include the Prospectus for each Fund and additional quantitative information updated on a daily basis, including, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or mid-point of the bid/ask spread at the time of the calculation of such NAV (''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV. On each Business Day, before commencement of trading in Shares on the Stock Exchange, the Fund will disclose on its Web site the identities and quantities of the Portfolio Instruments held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the Business Day.[24]

[22] If Shares are listed on NASDAQ, no Specialist will be contractually obligated to make a market in Shares. Rather, under NASDAQ's listing requirements, two or more Market Makers will be registered as Market Makers in Shares and required to make a continuous, two-sided market or face regulatory sanctions. No Market Maker or Specialist will be an affiliated person, or an affiliated person of an affiliated person, of the Funds, except within the meaning of section 2(a)(3)(A) or (C) of the Act due solely to ownership of Shares, as discussed below.

[23] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or DTC Participants.

[24] Applicants note that under accounting procedures 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.

Applicants' Legal Analysis

1. Applicants request an 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.

2. 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 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 policy of each registered investment company concerned and the general provisions 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.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares will not be individually redeemable, Applicants request an order that would permit the Trust and any Fund to register as an open-end management investment company and redeem Shares in Creation Units only. Applicants state that investors may purchase Shares in Creation Units from each Fund and redeem Creation Units from each Fund. Applicants further state that because the market price of Creation Units will be disciplined by arbitrage opportunities, investors should be able to sell Shares in the secondary market at prices that do not vary materially from their NAV.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through a principal underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming, or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in the Prospectus, and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) Prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers resulting from sales at different prices, and (c) assure an orderly distribution of investment company shares by eliminating price competition from Brokers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve the Funds as parties and cannot result in dilution of an investment in Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, Applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, Applicants

contend that the proposed distribution system will be orderly because arbitrage activity should ensure that the differences between the market price of Shares and their NAV remain low.

Section 22(e) of the Act

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants observe that settlement of redemptions of Creation Units of the Global Funds is contingent not only on the settlement cycle of the U.S. securities markets but also on the delivery cycles present in foreign markets in which those Funds invest. Applicants have been advised that, under certain circumstances, the delivery cycles for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, will require a delivery process of up to 14 calendar days. Applicants therefore request relief from section 22(e) in order to provide payment or satisfaction of redemptions within the maximum number of calendar days required for such payment or satisfaction in the principal local markets where transactions in the Redemption Instruments of each Global Fund customarily clear and settle, but in all cases no later than 14 calendar days following the tender of a Creation Unit.[25] With respect to Future Funds that are Global Funds, Applicants seek the same relief from section 22(e) only to the extent that circumstances exist similar to those described in the application. Except as disclosed in the statement of additional information (''SAI'') for any Future Fund for analogous dates in subsequent years, deliveries of redemption proceeds for Global Funds are expected to be made within seven days.

8. Applicants submit that Congress adopted section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds. Applicants state that allowing redemption payments for Creation Units of a Fund to be made within a maximum of 14 calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants state the SAI will disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of redemption proceeds in seven calendar days and the maximum number of days, up to fourteen calendar days, needed to deliver the proceeds for each affected Global Fund. Applicants are not seeking relief from section 22(e) with respect to Global Funds that do not effect redemptions in-kind.

Section 12(d)(1) of the Act

9. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring shares of an investment company if the securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter, or any other broker or dealer from selling its shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

10. Applicants request relief to permit Investing Funds (as defined below) to acquire Shares in excess of the limits in section 12(d)(l)(A) of the Act and to permit the Funds, their principal underwriters and any Brokers to sell Shares to Investing Funds in excess of the limits in section 12(d)(l)(B) of the Act. Applicants request that these exemptions apply to: (a) any Fund as well as any principal underwriter for the Fund and any Brokers selling Shares of a Fund to an Investing Fund; and (b) each management investment company or unit investment trust registered under the Act that is not part of the same ''group of investment companies'' within the meaning of section 12(d)(1)(G)(ii) of the Act as the Funds, and that enters into a FOF Participation Agreement (as defined below) with a Fund (such management investment companies are referred to herein as ''Investing Management Companies,'' such unit investment trusts are referred to herein as ''Investing Trusts,'' and Investing Management Companies and Investing Trusts together are referred to herein as ''Investing Funds'').[26] Investing Funds do not include the Funds. Each Investing Trust will have a sponsor (''Sponsor'') and each Investing Management Company will have an investment adviser within the meaning of section 2(a)(20)(A) of the Act (''Investing Fund Advisor'') that does not control, is not controlled by or under common control with the Investment Manager or any Investment Advisor. Each Investing Management Company may also have one or more investment advisers within the meaning of section 2(a)(20)(B) of the Act (each, an ''Investing Fund Sub-Advisor''). Each Investing Fund Advisor and any Investing Fund Sub-Advisor will be registered as an investment adviser under the Advisers Act.

11. Applicants submit that the proposed conditions to the requested relief are designed to address the concerns underlying the limits in section 12(d)(1), which include concerns about undue influence, excessive layering of fees and overly complex structures.

12. Applicants propose a condition to prohibit an Investing Fund or Investing Fund Affiliate[27] from causing an investment by an Investing Fund in a Fund to influence the terms of services or transactions between an Investing Fund or an Investing Fund Affiliate and the Fund or Fund Affiliate. Applicants propose a condition to limit the ability of the Investing Fund Advisor, or Sponsor, any person controlling, controlled by or under common control with such Investing Fund Advisor or Sponsor, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by the Investing Fund Advisor, the Sponsor, or any person controlling, controlled by, or under common control with such Investing Fund Advisor or Sponsor (''Investing Fund's Advisory Group'') from (individually or in the aggregate) controlling a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Investing Fund Sub-Advisor, any person controlling, controlled by, or under common control with the Investing Fund Sub-Advisor, and any investment

[25] Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations that it may otherwise have under rule 15c6–1 under the Exchange Act. Rule 15c6–1 requires that most securities transactions be settled within three business days of the trade date.

[26] Applicants anticipate that there may be Investing Funds that are not part of the same group of investment companies as the Funds, but are subadvised by the Investment Manager or an Investment Advisor.

[27] An ''Investing Fund Affiliate'' is defined as the Investing Fund Advisor, Investing Fund Sub-Advisor, Sponsor, promoter and principal underwriter of an Investing Fund, and any person controlling, controlled by or under common control with any of these entities. A ''Fund Affiliate'' is defined as an investment adviser, promoter or principal underwriter of a Fund and any person controlling, controlled by or under common control with any of these entities.

company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Investing Fund Sub-Advisor or any person controlling, controlled by or under common control with the Investing Fund Sub-Advisor (''Investing Fund's Sub-Advisory Group'').

13. Applicants propose other conditions to limit the potential for an Investing Fund and certain affiliates of an Investing Fund (including Underwriting Affiliates) to exercise undue influence over a Fund and certain of its affiliates, including that no Investing Fund or Investing Fund Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting''). An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Investing Fund Advisor, Investing Fund Sub-Advisor, employee or Sponsor of the Investing Fund, or a person of which any such officer, director, member of an advisory board, Investing Fund Advisor or Investing Fund Sub-Advisor, employee or Sponsor is an affiliated person. An Underwriting Affiliate does not include any person whose relationship to the Fund is covered by section 10(f) of the Act.

14. Applicants propose several conditions to address the concerns regarding layering of fees and expenses. Applicants note that the board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of section 2(a)(19) of the Act (''disinterested directors or trustees''), will be required to find that the advisory fees charged under any advisory contract with the Investment Manager or with any Investment Advisor are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund in which the Investing Management Company may invest. In addition, an Investing Fund Advisor, trustee of an Investing Trust (''Trustee'') or Sponsor, as applicable, will waive fees otherwise payable to it by the Investing Fund in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–1 under the Act) received from a Fund by the Investing Fund Advisor, Trustee or Sponsor or an affiliated person of the Investing Fund Advisor, Trustee or Sponsor, other than any advisory fees paid to the Investing Fund Advisor, Trustee or Sponsor or its affiliated person by a Fund, in connection with the investment by the Investing Fund in the Fund. Applicants also propose a condition to prevent any sales charges or service fees on shares of an Investing Fund from exceeding the limits applicable to a fund of funds set forth in NASD Conduct Rule 2830.[28]

15. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that a Fund will be prohibited from acquiring securities of any investment company or company relying on sections 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares of other investment companies for short-term cash management purposes.

16. To ensure that the Investing Funds understand and comply with the terms and conditions of the requested order, any Investing Fund that intends to invest in a Fund in reliance on the requested order will be required to enter into a participation agreement (''FOF Participation Agreement'') with the Fund. The FOF Participation Agreement will include an acknowledgment from the Investing Fund that it may rely on the order only to invest in the Funds and not in any other investment company.

Sections 17(a)(1) and (2) of the Act

17. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such a person (''second tier affiliate''), from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' to include any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the other person and any person directly or indirectly controlling, controlled by, or under common control with, the other person. Section 2(a)(9) of the Act defines ''control'' as the power to exercise a controlling influence over the management or policies of a company and provides that a control relationship will be presumed where one person owns more than 25% of another person's voting securities. Each Fund may be deemed to be controlled by the Investment Manager or any Investment Advisor and hence be an affiliated person of each other Fund. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by the Investment Manager or an Investment Advisor (an ''Affiliated Fund'').

18. Applicants request an exemption under sections 6(c) and 17(b) of the Act from sections 17(a)(1) and 17(a)(2) of the Act to permit in-kind purchases and redemptions of Creation Units by persons that are affiliated persons or second tier affiliates of the Funds solely by virtue of one or more of the following: (a) Holding 5% or more, or in excess of 25% of the outstanding Shares of one or more Funds; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25% of the Shares of one or more Affiliated Funds.[29] Applicants also request an exemption in order to permit a Fund to sell its Shares to, and redeem its Shares from, an Investing Fund and to engage in any accompanying in-kind transactions with certain Investing Funds of which the Funds are affiliated persons or a second-tier affiliates.[30]

19. Applicants assert that no useful purpose would be served by prohibiting such affiliated persons from making in-kind purchases or in-kind redemptions of Shares of a Fund in Creation Units. Except as described above, the Deposit Instruments and Redemption Instruments available for a Fund will be the same for all purchasers and redeemers, respectively, and will correspond *pro rata* to the Fund's Portfolio Instruments. Both the deposit procedures for in-kind purchases of Creation Units and the redemption

[28] Any references to NASD Conduct Rule 2830 include any successor or replacement rule to NASD Conduct Rule 2830 that may be adopted by the Financial Industry Regulatory Authority.

[29] Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an affiliated person, or an affiliated person of an affiliated person, of an Investing Fund because an investment adviser to the Funds is also an investment adviser to an Investing Fund.

[30] Applicants expect most Investing Funds will purchase Shares in the secondary market and will not purchase Creation Units directly from a Fund. To the extent that purchases and sales of Shares occur in the secondary market and not through principal transactions directly between an Investing Fund and a Fund, relief from section 17(a) would not be necessary. However, the requested relief would apply to direct sales of Shares in Creation Units by a Fund to an Investing Fund and redemptions of those Shares. The requested relief is also intended to cover any in-kind transactions that may accompany such sales and redemptions.

procedures for in-kind redemptions will be effected in exactly the same manner for all purchases and redemptions. Deposit Instruments and Redemption Instruments will be valued in the same manner as those Portfolio Instruments currently held by the relevant Funds. Therefore, Applicants state that the in-kind purchases and redemptions create no opportunity for affiliated persons or the Applicants to effect a transaction detrimental to other holders of Shares of a Fund. Applicants do not believe that in-kind purchases and redemptions will result in abusive self-dealing or overreaching of any Fund.

20. Applicants also submit that the sale of Shares to and redemption of Shares from an Investing Fund meets the standards for relief under sections 17(b) and 6(c) of the Act. Applicants note that any consideration paid for the purchase or redemption of Shares directly from a Fund will be based on the NAV of the Fund in accordance with policies and procedures set forth in the Fund's registration statement.[31] Applicants also state that the proposed transactions are consistent with the general purposes of the Act and appropriate in the public interest.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. Actively Managed Exchange-Traded Fund Relief

1. As long as a Fund operates in reliance on the requested order, the Shares of the Fund will be listed on a Stock Exchange.

2. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that the Shares are not individually redeemable and that owners of the Shares may acquire those Shares from the Fund and tender those Shares for redemption to the Fund in Creation Units only.

3. The Web site for the Funds, which is and will be publicly accessible at no charge, will contain, on a per Share basis, for each Fund the prior Business Day's NAV and the market closing price or Bid/Ask Price, and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

4. On each Business Day, before commencement of trading in Shares on the Stock Exchange, the Fund will disclose on its Web site the identities and quantities of the Portfolio Instruments held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the Business Day.

5. The Investment Manager or any Investment Advisor, directly or indirectly, will not cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Fund) to acquire any Deposit Instrument for the Fund through a transaction in which the Fund could not engage directly.

6. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of actively managed exchange-traded funds.

B. Section 12(d)(1) Relief

1. The members of the Investing Fund's Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The members of the Investing Fund's Sub-Advisory Group will not control (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Investing Fund's Advisory Group or the Investing Fund's Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of a Fund, it will vote its Shares of the Fund in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Investing Fund's Sub-Advisory Group with respect to a Fund for which the Investing Fund Sub-Advisor or a person controlling, controlled by or under common control with the Investing Fund Sub-Advisor acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Investing Fund or Investing Fund Affiliate will cause any existing or potential investment by the Investing Fund in a Fund to influence the terms of any services or transactions between the Investing Fund or an Investing Fund Affiliate and the Fund or a Fund Affiliate.

3. The board of directors or trustees of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to assure that the Investing Fund Advisor and any Investing Fund Sub-Advisor are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or an Investing Fund Affiliate from a Fund or a Fund Affiliate in connection with any services or transactions.

4. Once an investment by an Investing Fund in the Shares of a Fund exceeds the limit in section 12(d)(1)(A)(i) of the Act, the Board of the Fund, including a majority of the disinterested Board members, will determine that any consideration paid by the Fund to the Investing Fund or an Investing Fund Affiliate in connection with any services or transactions: (i) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund; (ii) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Investing Fund Advisor, or Trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Investing Fund in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b–1 under the Act) received from a Fund by the Investing Fund Advisor, or Trustee or Sponsor, or an affiliated person of the Investing Fund Advisor, or Trustee or Sponsor, other than any advisory fees paid to the Investing Fund Advisor, or Trustee, or Sponsor, or its affiliated person by the Fund, in connection with the investment by the Investing Fund in the Fund. Any Investing Fund Sub-Advisor will waive fees otherwise payable to the Investing Fund Sub-Advisor, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from a Fund by the Investing Fund Sub-Advisor, or an affiliated person of the Investing Fund Sub-Advisor, other than any advisory fees paid to the Investing Fund Sub-Advisor or its affiliated person by the Fund, in connection with the investment by the Investing Management Company in the Fund made at the direction of the Investing

[31] Applicants acknowledge that the receipt of compensation by (a) an affiliated person of an Investing Fund, or an affiliated person of such person, for the purchase by the Investing Fund of Shares of the Fund or (b) an affiliated person of a Fund, or an affiliated person of such person, for the sale by the Fund of its Shares to an Investing Fund, may be prohibited by section 17(e)(1) of the Act. The FOF Participation Agreement also will include this acknowledgment.

Fund Sub-Advisor. In the event that the Investing Fund Sub-Advisor waives fees, the benefit of the waiver will be passed through to the Investing Management Company.

6. No Investing Fund or Investing Fund Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an Affiliated Underwriting.

7. The Board of a Fund, including a majority of the disinterested Board members, will adopt procedures reasonably designed to monitor any purchases of securities by the Fund in an Affiliated Underwriting, once an investment by an Investing Fund in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Investing Fund in the Fund. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Fund; (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Fund in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to assure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders.

8. Each Fund will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by an Investing Fund in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the Board's determinations were made.

9. Before investing in a Fund in excess of the limits in section 12(d)(1)(A), an Investing Fund will execute a FOF Participation Agreement with the Fund stating that their respective boards of directors or trustees and their investment advisers, or Trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in shares of a Fund in excess of the limit in section 12(d)(1)(A)(i), an Investing Fund will notify the Fund of the investment. At such time, the Investing Fund will also transmit to the Fund a list of the names of each Investing Fund Affiliate and Underwriting Affiliate. The Investing Fund will notify the Fund of any changes to the list as soon as reasonably practicable after a change occurs. The Fund and the Investing Fund will maintain and preserve a copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company, including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund in which the Investing Management Company may invest. These findings and their basis will be recorded fully in the minute books of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of an Investing Fund will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Fund relying on this section 12(d)(1) relief will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund to purchase shares of other investment companies for short-term cash management purposes.

C. Compliance Obligations

1. Any advisory contract between a Fund and the Investment Manager will include provisions that obligate the Investment Manager (i) to comply with the terms and conditions of the Order and (ii) to monitor and enforce compliance by any Investment Advisor with the terms and conditions of the Order, including any terms and conditions that may relate to investment activity of the Investment Advisor with respect to the Fund.

2. Any advisory contract between a Fund and an Investment Advisor will include provisions that obligate the Investment Advisor to comply with the terms and conditions of the Order. Before a Fund enters into an advisory contract with an Investment Advisor, the Investment Manager and the Investment Advisor will execute a Compliance Agreement (i) obligating the Investment Advisor to comply with the terms and conditions of the Order, (ii) obligating the Investment Manager to monitor compliance by the Investment Advisor with the terms and conditions of the Order, and (iii) establishing the Investment Manager's power to enforce compliance by the Investment Advisor with the terms and conditions of the Order.

3. The Board, including a majority of the trustees that are not interested persons within the meaning of Section 2(a)(19) of the 1940 Act, shall review and approve each Compliance Agreement annually. The Chief Compliance Officer of the Investment Manager will conduct reviews at least annually to ensure compliance by the Investment Manager and each Investment Advisor with the terms and conditions of the requested Order. The Chief Compliance Officer of each Investment Advisor will conduct reviews at least annually to ensure compliance by such Investment Advisor with the terms and conditions of the requested Order. Their reports shall be reviewed at least annually by the Fund's Chief Compliance Officer and the Fund's Board in connection with the Board's consideration of the Compliance Agreement and in connection with its Section 15 review and approval of advisory contracts with the Investment Manager and each Investment Advisor.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11146 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69520; File No. 4–661]

Credit Ratings Roundtable

AGENCY: Securities and Exchange Commission.

ACTION: Notice of roundtable discussion location change.

SUMMARY: This notice announces the change of location of the May 14, 2013, Credit Ratings Roundtable that was published in the April 29, 2013 **Federal Register** (78 FR 25101 through 25102). The new location of the roundtable discussion is Room L–002 (the Auditorium) at the Securities and Exchange Commission's headquarters located at 100 F Street NE., in Washington, DC 20549. The public is invited to observe the roundtable discussion. Seating will be available on a first-come, first-served basis. The roundtable discussion also will be available via webcast on the Commission's Web site at *www.sec.gov*.

DATES: The roundtable discussion will take place on May 14, 2013. The Commission will accept comments regarding issues addressed at the roundtable until June 3, 2013.

FOR FURTHER INFORMATION CONTACT: Scott Davey at (212) 336–0075, Office of Credit Ratings, Securities and Exchange Commission, 3 World Financial Center, New York, NY 10281–1022.

SUPPLEMENTARY INFORMATION: On April 29, 2013, we published a notice in the **Federal Register** (78 FR 25101 through 25102) that announced a May 14, 2013 roundtable to discuss various matters related to credit ratings.

Dated: May 6, 2013.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2013–11082 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69523; File No. SR–NYSEArca–2013–41]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Establishing a Schedule of the NYSE Arca Options Proprietary Market Data Fees

May 6, 2013.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 25, 2013, 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 establish a schedule of the NYSE Arca Options Proprietary Market Data Fees (''Market Data Fee Schedule''). 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 Exchange proposes to establish a Market Data Fee Schedule. The market data fees on the proposed Market Data Fee Schedule for NYSE ArcaBook for Arca Options have been previously filed with the Commission.[4] NYSE ArcaBook for Arca Options includes Trades, Top of Book, Depth of Book, Complex, Series Status, and Order Imbalance data. At this time, the Exchange does not offer separate pricing for each of the individual data products. The Exchange is proposing the Market Data Fee Schedule in order to provide greater transparency to its customers.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) [5] of the Act, in general, and furthers the objectives of Section 6(b)(5) [6] of the Act, 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, and it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange believes that establishing the Market Data Fee Schedule will remove impediments to and help perfect a free and open market by providing greater transparency for the Exchange's customers. In addition, the market data fees have been previously filed with the Commission.[7]

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 because the Exchange is merely establishing a Market Data Fee Schedule for fees that have been previously filed with the Commission.[8]

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

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, 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

[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. 68005 (Oct. 9, 2012), 77 FR 63362 (Oct. 16, 2012) (SR–NYSEArca–2012–106).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *See supra* n.4.

[8] *Id.*

Section 19(b)(3)(A)[9] of the Act and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[11] However, Rule 19b–4(f)(6)(iii)[12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Exchange believes that the proposed rule change will make the Exchange's proprietary market data fees more transparent. The Commission believes that permitting the Exchange to make this change without delay is consistent with the protection of investors and the public interest. Accordingly, the Commission designates the proposed rule change to be operative upon filing.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–2013–41 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca-2013–41. 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 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 publicly available. All submissions should refer to File Number SR–NYSEArca–2013–41 and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11174 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] *Id.*

[13] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69517; File No. SR–BOX–2013–22]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7170 (Obvious and Catastrophic Errors)

May 6, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 26, 2013, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''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 from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7170 (Obvious and Catastrophic Errors). Specifically, the Exchange proposes to amend Rule 7170(h)(2) to permit the nullification of trades involving catastrophic errors in certain situations specified below. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposal is to help market participants better manage their risk by addressing the situation where, under current rules, a trade can be adjusted to a price outside of a customer's limit. Specifically, the Exchange proposes to amend Rule 7170(h) to enable a Public Customer[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Under BOX Rule 100(a)(51) the term ''Public Customer'' means a person that is not a broker or dealer in securities. This includes Professionals under BOX Rule 100(a)(50), but not broker-dealers or Market Makers.

who is the contra-side to a trade that is deemed to be a catastrophic error to have the trade nullified in instances where the adjusted price would violate the Public Customer's limit price. Only if the Public Customer, or his agent, affirms the Public Customer's willingness to accept the adjusted price through the Public Customer's limit price within 20 minutes of notification of the catastrophic error ruling would the trade be adjusted; otherwise it would be nullified. Today, all catastrophic error trades are adjusted, not nullified, on all of the options exchanges. This is a competitive filing that is based on a proposal recently submitted by NASDAQ OMX PHLX LLC (''PHLX'') and approved by the Commission.[5]

Background

Currently, Rule 7170 governs obvious and catastrophic errors. Obvious errors are calculated under the rule by determining a theoretical price and determining, based on objective standards, whether the trade should be nullified or adjusted. The rule also contains a process for requesting an obvious error review. Certain more substantial errors may fall under the category of a catastrophic error, for which a longer time period is permitted to request a review and for which trades can only be adjusted (not nullified). Trades are adjusted pursuant to an adjustment table that, in effect, assesses an adjustment penalty. By adjusting trades above or below the theoretical price, the Rule assesses a ''penalty'' in that the adjustment price is not as favorable as the amount the party making the error would have received had it not made the error.

Proposal

At this time, the Exchange proposes to change the catastrophic error process to permit certain trades to be nullified. The definition and calculation of a catastrophic error would not change.[6] First whether a transaction is a catastrophic error is determined by the Exchange's MRC,[7] if both parties to the trade are Public Customers then the trade would be adjusted under the current rule. However, if only one of the parties is a Public Customer, then the adjusted price would be compared to the limit price of the order. If the adjusted price would violate the limit price (in other words, be higher than the limit price if it is a buy and lower than the limit price if it is a sell order), then the Public Customer would be offered an opportunity to nullify the trade. If the Public Customer (or the Public Customer's broker-dealer agent) does not respond within 20 minutes, the trade would be adjusted under the current rule.

These changes should ensure that a Public Customer is not forced into a situation where the original limit price is violated and thereby the Public Customer is forced to spend additional dollars for a trade at a price the customer had no interest in trading and may not be able to afford.

EXAMPLE 1—Resting Public Customer forced to adjust through his limit price and would prefer nullification.

Day 1

8:00:00 a.m. (pre-market)

Customer A enters order on BOX to buy 10 GOOG May 750 puts for $25 (cost of $25,000, Customer has $50,000 in his trading account).

10:00:00 a.m.

GOOG trading at $750
May 750 puts $29.00–$31.00 (100×100) on all exchanges

10:04:00 a.m.

GOOG drops to $690
May 750 puts $25–$100 (10×10) BOX
May 750 puts $20–$125 (10×10) CBOE
May 750 puts $10–$200 (100×100) on all other exchanges

10:04:01 a.m.

Customer B enters order to sell 10 May 750 puts for $25 (credit of $25,000)

10:04:01 a.m.

10 May 750 puts execute at $25 ($35 under parity)[8] with Customer A buying and Customer B selling.

10:04:02 a.m. (1 second later)

GOOG trading $690
May 750 puts $75–$78 (100×100) BOX
May 750 puts $75–$80 (10×10) CBOEMay 750 puts $70–$80 (100×100) All other exchanges

No obvious error is filed within 20 minute notification time required by rule. If this had been an obvious error review, the trade would have been nullified in accordance with Rule 7170 because one of the parties to the trade was a non-market maker.

4:00:00 p.m. (the close)

GOOG trading $710
May 750 puts $60–$63 (100×100) BOX
May 750 puts $55–$70 (10×10) CBOE
May 750 puts $50–$70 (100×100) All other exchanges

Day 2

8:00:00 a.m. (pre-market)

Customer B, submits S10 GOOG May 750 puts at $25 under Catastrophic Review. Trade meets the criteria of Catastrophic Error and is adjusted to $68 ($75 (the 10:04:02 a.m. price less $7 adjustment penalty).

9:30:00 a.m. (the opening)

GOOG trading $725
May 750 puts open $48.00–$51.00 (100×100) on all exchanges

Under current rule:

Without a choice, Customer A is forced to spend $68 (cost of $68,000, with only $25,000 in his account)
Puts are now trading $48, so Customer A shows a loss of $20,000 ($68 less $48×10 contracts × 100 multiplier)

Under proposed rule:

Customer A would be able to choose to have the B10 GOOG May 750 puts nullified avoiding both a loss, and an expenditure of capital exceeding the amount in his account.
Customer B would be relieved of the obligation to sell the puts at 25 because the trade would be nullified.

EXAMPLE 2—Resting Public Customer trades, sells out his position, thus would choose to keep the adjusted trade and avoid nullification.

Day 1

8:00:00 a.m. (pre-market)

Customer A enters order on BOX to Buy 10 BAC April 7.00 calls for $.01 (cost of $10 total. (Customer has $3,000 in his account).

10:00:00 a.m.

BAC trading $11
April 7 calls $4.50–$4.70 (100×100) on all exchanges

10:04:00 a.m.

BAC Trading $11
April 7 calls $.01–$4.70 (10×10) BOX
April 7 calls
$4.50–$4.70 (10×10) CBOE
April 7 calls $4.50–$4.70 (10×10)) All other exchanges

10:04:01 a.m.

Customer B enters order to sell 10 April 7 calls at $.01 on BOX with an ISO indicator (which allows trade through)

[5] *See* Securities Exchange Act Release No. 69304 (April 4, 2013), 78 FR 21482 (April 10, 2013) (Order Approving SR–Phlx–2013–005).

[6] Nor is the definition or process for obvious errors changing.

[7] The MRC is the BOX Market Regulation Center.

[8] Parity is the intrinsic value of an option when it is in-the-money. With respect to puts, it is calculated by subtracting the price of the underlying from the strike price of the put. With respect to calls, it is calculated by subtracting the strike price from the price of the underlying.

10:04:01 a.m.

10 April 7 calls execute at $.01 on BOX Customer A buying and Customer B selling.

10:04:02 a.m. (1 second later)

BAC is $11
April 7 calls $4.50–$4.70 (10×10) BOX April 7 calls
$4.50–$4.70 (10×10) CBOE
April 7 calls $4.50–$4.70 (10×10)) All other exchanges

No obvious error is filed within 20 minute notification time required by rule. If this had been an obvious error review, the trade would have been nullified.

11:00:00 a.m.

BAC trading $9.60
April 7 calls $3.00–$3.25 (10×10) BOX April 7 calls
$3.00–$3.25 (10×10) CBOE
April 7 calls $3.00–$3.25 (10×10)) All other exchanges
Customer A sells 10 April 7 calls at $3.00 (a total credit of $3,000 for a $2,990 profit)

3:00:00 p.m.

BAC trading $12.80
April 7 calls $5.80–$6.00 (10×10) BOX April 7 calls
$5.80–$6.00 (10×10) CBOE
April 7 calls $5.80–$6.00 (10×10)) All other exchanges
Customer A has now no position and would be at risk of a loss if nullified.

3:20:00 p.m.

Customer B submits S10 BAC April 7 calls at $.01 under Catastrophic Error Review. Trade meets the criteria of Catastrophic Error and is adjusted to $2.50 ($4.50 (the 10:04:02 a.m. price) less $2 adjustment penalty).

Impact:

Under current Rule: Customer A would be adjusted to $2.50 ($4.50 (the 10:04:02 a.m. price) less $2 adjustment penalty).

Under Proposed rule:

Illustrating the need for a choice, Customer A chooses within 20 minutes to accept an adjustment to $2.50 instead of a nullification, locking in a gain of $500 instead of $2.990 (B 10 at $2.50 vs. S10 at $3.00).
If not given a choice, Customer A would be naked short 10 calls at $3.00 that are now offered at $6.00 (a $3,000 loss).

These examples illustrate the need for the Public Customer to have a choice in order to manage his risk. By applying a notification time limit of 20 minutes, it lessens the likelihood that the Public Customer will try to let the direction of the market for that option dictate his decision for a long period of time, thus exposing the contra side to more risk. This 20 minute time period is akin to the notification period currently used in the rule respecting the notification period for starting the obvious error process for non-Market Maker Options Participants.[9]

For a market maker or a broker-dealer, the penalty that is part of the price adjustment process is usually enough to offset the additional dollars spent, and they can often trade out of the position with little risk and a potential profit. For a Public Customer who is not immersed in the day-to-day trading of the markets, this risk may be unacceptable. A Public Customer is also less likely to be watching trading activity in a particular option throughout the day and less likely to be closely focused on the execution reports the Public Customer receives after a trade is executed. Accordingly, the Exchange believes that it is fair and reasonable, and consistent with statutory standards, to change the procedure for catastrophic errors for Public Customers and not for other Participants.

The Exchange believes that the proposal is a fair way to address the issue of a Public Customer's limit price, yet still balance the competing interests of certainty that trades stand versus dealing with true errors. In 2009, the Exchange amended Rule 7170 to adopt the catastrophic error provision. In doing so, the Exchange stated that it had ''weighed carefully the need to assure that one market participant is not permitted to receive a windfall at the expense of another market participant that made an Obvious Error, against the need to assure that market participants are not simply being given an opportunity to reconsider poor trading decisions. The Exchange stated that, while it believed that the Obvious Error Rule strikes the correct balance in most situations, in some extreme situations, Participants may not be aware of errors that result in very large losses within the time periods currently required under the rule. In this type of extreme situation, the Exchange believes Participants should be given more time to seek relief so that there is a greater opportunity to mitigate very large losses and reduce the corresponding large wind-falls. However, to maintain the appropriate balance, the Exchange believes Participants should only be given more time when the execution price is much further away from the theoretical price than is required for Obvious Errors so that relief is only provided in extreme circumstances.'' [10]

The Exchange believes that this proposal is consistent with those principles because it strikes the aforementioned balance. The Exchange is proposing to amend Rule 7170 to eliminate the risk associated with Public Customers receiving an adjustment to a trade that is outside of the limit price of their order, when there is a catastrophic error ruling respecting their trade. The new provision would continue to entail specific and objective procedures. Furthermore, the new provision more fairly balances the potential windfall to one market participant against the potential reconsideration of a trading decision under the guise of an error.

The obvious and catastrophic error rules of the options exchanges are similar, especially with respect to only adjusting trades that result in a catastrophic error. Nevertheless, the Exchange believes, based on the aforementioned example, the recently approved Phlx filing, and Participant requests that this aspect of the catastrophic error process should change, as explained above. Relatedly, members of SIFMA's Options Committee also expressed concern during a recent meeting that this particular outcome may not be appropriate. Accordingly, the Exchange has determined to amend the rule.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(5) of the Act [12] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by helping Participants better manage the risk associated with potential erroneous trades. Specifically, the Exchange believes that the proposal is consistent with these principles because it provides a fair process for Public Customers to address catastrophic errors involving a limit order. In particular, the proposal still permits nullification in certain situations. Further, it gives Public Customers a choice. For two reasons, the Exchange does not believe that the proposal is unfairly

[9] *See* BOX Rule 7170(g)(1).

[10] *See* Securities Exchange Act Release No. 59197 (January 5, 2009), 74 FR 969 (January 9, 2009)(SR–BSE–2008–52)(Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Catastrophic Errors).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

discriminatory, even though it offers some Participants (Public Customers) a choice as to whether a trade is nullified or adjusted, while other Participants (Broker-Dealers and Market Makers) will continue to have all of their catastrophic errors adjusted. First, the rule currently differentiates among Participants: the notification period to begin the obvious error process is different for Market Makers and non-Market Maker Options Participants, and whether a trade is adjusted or busted also differs.[13] Second, options rules often treat Public Customers in a special way,[14] recognizing that Public Customers are not necessarily immersed in the day-to-day trading of the markets, less likely to be watching trading activity in a particular option throughout the day and may have limited funds in their trading accounts. Accordingly, differentiating among Participant types by permitting Public Customers to have a choice as to whether to nullify a trade involving a catastrophic error is not unfairly discriminatory, because it is reasonable and fair to provide Public Customers with additional options to protect themselves against the consequences of obvious errors.

The Exchange acknowledges that the proposal contains some uncertainty regarding whether a trade will be adjusted or nullified, depending on whether one of the parties is a Public Customer, because a person would not know, when entering into the trade, whether the other party is or is not a Public Customer. The Exchange believes that the proposal nevertheless promotes just and equitable principles of trade and protects investors and the public interest, because it eliminates a more serious uncertainty in the rule's operation today, which is *price* uncertainty. Today, a Public Customer's order can be adjusted to a significantly different price, as the examples above illustrate, which is more impactful than the possibility of nullification. Furthermore, there is uncertainty in the current obvious error portion of Rule 7170 (as well as the rules of other options exchanges), which Participants have dealt with for a number of years. Specifically, Rule 7170(g)(2) provides that if it is determined that an Obvious Error has occurred: (A) where each party to the transaction is either a market maker on the Exchange, the execution price of the transaction will be adjusted by the MRC, unless both parties agree to nullify the transaction within ten minutes of being notified by the MRC of the Obvious Error; or (B) where at least one party to the transaction in which an Obvious Error occurred is not a market maker on the Exchange, the MRC will nullify the transaction, unless both parties agree to adjust the price of the transaction within 30 minutes of being notified by the MRC of the Obvious Error. Therefore, a market maker who prefers adjustments over nullification cannot guarantee that outcome, because, if he trades with a Public Customer, a resulting obvious error would only be adjusted if the Public Customer agreed to an adjustment. This uncertainty has been embedded in the rule and accepted by market participants. The Exchange believes that this proposal, despite the uncertainty based on whether a Public Customer is involved in a trade, is nevertheless consistent with the Act, because the ability to nullify a Public Customer's trade involving a catastrophic error should prevent the price uncertainty that mandatory adjustment under the current rule creates, which should promote just and equitable principles of trade and protect investors and the public interest.

The proposal sets forth an objective process based on specific and objective criteria and subject to specific and objective procedures. In addition, the Exchange has again weighed carefully the need to assure that one market participant is not permitted to receive a windfall at the expense of another market participant that made a catastrophic error, against the need to assure that market participants are not simply being given an opportunity to reconsider poor trading decisions. Accordingly, the Exchange has determined that introducing a nullification procedure for catastrophic errors is appropriate and consistent with the Act.

Consistent with Section 6(b)(8),[15] the Exchange also believes that the proposal does not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act, as described further below.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to the filing submitted by Phlx.[16] The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges and to establish uniform rules regarding catastrophic errors. Currently, most options exchanges have similar, although not identical, rules regarding catastrophic errors. To the extent that this proposal would result in the Exchange's rule being different, market participants may choose to route orders to the Exchange, helping the Exchange compete against other options exchanges for order flow based on its Public Customers service by having a process more responsive to current market needs. The proposal does not impose a burden on intra-market competition not necessary or appropriate in furtherance of the purposes of the Act, because, even though it treats different market participants differently, the Obvious and Catastrophic Errors rule has always been structured that way and adding the ability for Public Customers to choose whether a catastrophic error trade is nullified does not materially alter the risks faced by other market participants in managing the consequences of obvious errors. Overall, the proposal is intended to help market participants better manage the risk associated with potential erroneous options trades and does not impose a burden on competition.

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 comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

This proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, prior to the date of filing the proposed rule change as

[13] *See* Rule 7170(g)(1).

[14] For example, many options exchange priority rules treat Public Customers orders differently and some options exchanges only accept certain types of orders from Public Customers. Most options exchanges charge different fees for Public Customers.

[15] 15 U.S.C. 78f(b)(5).

[16] *See supra,* note 4.

required by Rule 19b–4(f)(6).[17] The proposed rule change is substantially similar in all material respects to a proposal submitted by Phlx that was recently approved by the Commission.[18] The Exchange believes that this proposed rule change, which is essential for competitive purposes and to promote a free and open market for the benefit of investors, does not raise any new, unique or substantive issues from those raised in the Phlx filing.

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–BOX–2013–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2013–22. 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 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 publicly available. All submissions should refer to File Number SR–BOX–2013–22 and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11140 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 240.19b–4(f)(6).

[18] *See supra,* note 4.

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69525; File No. SR–BX–2013–033]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing of Proposed Rule Change To Amend BX Rule 4756 and Rule 4763 To Stipulate How Participants in the NASDAQ OMX BX Equities Market May Modify Previously Entered Orders and To Describe How Modified Orders Are Processed

May 6, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 25, 2013, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BX Rule 4756 (Entry and Display of Quotes and Orders) and Rule 4763 (Short Sale Price Test Pursuant to Rule 201 of Regulation SHO) to stipulate how Participants in the NASDAQ OMX BX Equities Market may modify previously entered orders and to describe how modified orders are processed.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is below; proposed new language is *italicized.*

* * * * *

4756. Entry and Display of Quotes and Orders

(a) Entry of Orders—Participants can enter orders into the System, subject to the following requirements and conditions:

(1)–(2) No change.

(3) Orders can be entered into the System (or previously entered orders cancelled *or modified*) from 7:00 a.m. until 7:00 p.m. Eastern Time. *Participants may modify a previously entered order without cancelling it or affecting the priority of the order on the book solely for the purpose of modifying the marking of a sell order as long, short, or short exempt; provided, however, that if an order is redesignated as short, a Short Sale Period is in effect under Rule 4763, and the order is not priced at a Permitted Price or higher under Rule 4763(d), the order will be cancelled. In addition, a partial cancellation of an order to reduce its share size will not affect the priority of the order on the book. All other modifications of orders will result in the replacement of the original order with a new order with a new time stamp.*

(b)–(c) No change.

* * * * *

4763. Short Sale Price Test Pursuant to Rule 201 of Regulation SHO

(a)–(c) No change.

(d) Re-pricing of Orders during Short Sale Period. *Except as provided below,* [D]*d*uring the Short Sale Period, short sale orders that are limited to the national best bid or lower and short sale market orders will be re-priced by the System one minimum allowable price increment above the current national best bid (''Permitted Price''). To reflect declines in the national best bid, the Exchange will continue to re-price a short sale order at the lowest Permitted Price down to the order's original limit price, or if a market order, until the order is filled. Non-displayed orders between the BX bid and offer will also be re-priced upward to a Permitted Price to correspond with a rise in the national best bid.

(1) No change.

(2) *During the Short Sale Period, if an order was entered as a long sale order or a short sale exempt order but is subsequently marked pursuant to Rule 4756(a)(3) as a short sale order, the System will cancel the order unless it is priced at a Permitted Price or higher.*

(e)–(f) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to stipulate how Participants in the NASDAQ OMX BX Equities Market may modify previously entered orders and to describe how modified orders are processed. Currently, Rule 4756 permits previously entered orders to be cancelled, a fact that has been interpreted by BX to allow a Participant to cancel an order in full or in part. However, new language is being added to the rule to make it clear that a partial cancellation of an order (*i.e.,* a reduction in the share size of the order) does not cause the order to lose priority on the BX book. BX believes that it is reasonable to allow the partial cancellation of an order without the order losing priority because the Participant that entered the order continues to express its willingness to trade at the price entered when the order first came onto the book. Moreover, if the order is displayed, other Participants quoting at the same price are aware of the priority of their orders relative to the partially cancelled order. While a partial cancellation may provide these other Participants with greater opportunities to provide a fill, BX does not believe that it would be reasonable for the Participants to jump ahead of an order with time priority merely because the size of the order has been reduced. Similarly, if the partially cancelled order is non-displayed, other Participants would have no awareness of its price, its original size, or its reduced size. Again, while other Participants at that price may have an increased opportunity to provide a fill when the order's size is reduced, they would not have an expectation that the priority of their orders would change vis-à-vis that of an order that arrived on the book at an earlier time. Finally, with respect to Participants seeking to access liquidity, the reduced size of the order would be disseminated (if a displayed order) or not disseminated (if a non-displayed order) via market data feeds, but these Participants would be indifferent as to the order's priority vis-à-vis other orders with the same price.

In addition, BX is modifying Rule 4756 to provide that a sell order may be modified in order to change its marking as long, short, or short exempt without affecting its priority on the book.[3] Participants sometimes wish to modify the marking of a sell order on the book due to changes in the Participant's holdings of the security in question. At present, such a modification may only be achieved by the cancellation of the existing order and its replacement with a new order with a different time stamp. BX believes that it is reasonable to allow the modification of an order for this purpose without affecting its priority, since the order's marking has no bearing on the timing of its entry onto the book vis-à-vis other orders at the same price.[4] In the event, however, that a long or short exempt order is redesignated as a short sale order and the security that is the subject of the order is in a Short Sale Period, as provided for in Rule 4763 and Rule 201 under Regulation SHO,[5] the order will be evaluated to determine whether its price would be a Permitted Price within the meaning of Rule 4763(d). If not, the order will be cancelled rather than repriced.[6] BX believes that cancelling the order under these circumstances is preferable to repricing it, because it alerts the Participant entering the order to the existence of the Short Sale Period and forces the Participant to evaluate its intentions with regard to the order.

Finally, BX is amending Rule 4756 to make it clear that all other modifications of previously submitted orders, including increases in size[7] and changes in price, will result in the cancellation of the original order and its replacement with a new order with a new time stamp. Although the addition of this rule language does not reflect a change in the way the BX system currently operates, BX believes that the clarity of the rule will be enhanced by including the new language. BX further believes that the functionality described by the rule language is important to ensuring that Participants cannot use an existing order unfairly to retain priority with respect to a materially different order.

2. Statutory Basis

BX believes that its proposal is consistent with Section 6(b) of the Act[8] in general, and furthers the objectives of Section 6(b)(5) of the Act[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Specifically, BX believes that permitting Participants to change the marking of sell orders without affecting their priority on the BX book will eliminate an aspect of the NASDAQ OMX BX Equities Market that had unnecessarily made it more difficult for posted sell orders to execute. Thus, the change will enhance the fairness and efficiency of the BX market without affecting the ability of Participants to comply with applicable regulatory requirements. In addition, the changes to the rule that describe the effect of a partial order cancellation promote the clarity of the rule with respect to the ability of a Participant to reduce the size of an existing order without affecting its priority. BX further believes that allowing an order to retain priority under these conditions is consistent with the operation of a free and open market and the protection of investors and the public interest, since the Participant that entered an order that is partially cancelled has nevertheless expressed a continued willingness to trade at a specified price, and therefore should retain priority over Participants that joined that price at a later time. Finally, BX believes that the proposed addition of language to clearly stipulate that all other order modifications will result in the cancellation and replacement of the original order with a new order with new time priority is consistent with the protection of investors and the public interest because the new language will make clear an existing feature of the market that BX believes is important to ensuring that Participants cannot use an existing order unfairly to retain priority

[3] The proposed rule does not affect Participants' obligations contained in Regulation SHO under the Act, and Participants must continue to comply with such obligations, including the order marking and locate requirements. *See* 17 CFR 242.200 *et seq.*

[4] A change to the marking of the order would be effected through the submission of a ''modify order'' message.

[5] 17 CFR 242.201.

[6] If an order originally marked as long or short is marked as short exempt, the order will not be cancelled or repriced. Rule 4763(f).

[7] BX reminds Participants that if a seller increases the size of a pending sell order, the resulting modified order is considered a new order and must be marked by the broker-dealer to reflect the seller's net position at the time of order modification pursuant to Rule 200 of Regulation SHO.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

with respect to a materially different order.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX 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. Specifically, BX believes that the change with respect to allowing Participants to modify the long, short, or short exempt marking of a sell order without affecting its priority will assist BX in competing with the BATS Exchange and the BATS Y-Exchange, which already allow their Participants to do so. BX further believes that the other changes will not have any effect on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11] 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–BX–2013–033 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2013–033. 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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; 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–BX–2013–033 and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11175 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69524; File No. SR–NYSEMKT–2013–35]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Establishing a Schedule of the NYSE Amex Options Proprietary Market Data Fees

May 6, 2013.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on April 25, 2013, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') 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 establish a schedule of the NYSE Amex Options Proprietary Market Data Fees (''Market Data Fee Schedule''). 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 Exchange proposes to establish a Market Data Fee Schedule. The market

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

data fees on the proposed Market Data Fee Schedule for NYSE ArcaBook for Amex Options have been previously filed with the Commission.[4] NYSE ArcaBook for Amex Options includes Trades, Top of Book, Depth of Book, Complex, Series Status, and Order Imbalance data. At this time, the Exchange does not offer separate pricing for each of the individual data products. The Exchange is proposing the Market Data Fee Schedule in order to provide greater transparency to its customers.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[5] of the Act, in general, and furthers the objectives of Section 6(b)(5)[6] of the Act, 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, and it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange believes that establishing the Market Data Fee Schedule will remove impediments to and help perfect a free and open market by providing greater transparency for the Exchange's customers. In addition, the market data fees have been previously filed with the Commission.[7]

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 because the Exchange is merely establishing a Market Data Fee Schedule for fees that have been previously filed with the Commission.[8]

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.

[4] *See* Securities Exchange Act Release No. 68004 (Oct. 9, 2012), 77 FR 62582 (Oct. 15, 2012) (SR–NYSEMKT–2012–49).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *See supra* n. 4.

[8] *Id.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, 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)[9] of the Act and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[11] However, Rule 19b–4(f)(6)(iii)[12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Exchange believes that the proposed rule change will make the Exchange's proprietary market data fees more transparent. The Commission believes that permitting the Exchange to make this change without delay is consistent with the protection of investors and the public interest. Accordingly, the Commission designates the proposed rule change to be operative upon filing.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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.

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] *Id.*

[13] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–NYSEMKT–2013–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2013–35. 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 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 publicly available. All submissions should refer to File Number SR–NYSEMKT–2013–35 and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11176 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69519; File No. SR–NSX–2013–02]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Order Granting Approval of Proposed Rule Change To Adopt a New Order Type Called the ''Auto-Ex Only'' Order and Add New Definitions Regarding Automatic Execution Mode and Automatic Execution Orders

May 6, 2013.

I. Introduction

On January 23, 2013, National Stock Exchange, Inc. (''Exchange'' or ''NSX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a new order type called the ''Auto-Ex Only'' order and to add new definitions regarding automatic execution (''Auto Ex'') mode and Auto Ex orders. The proposed rule change was published for comment in the **Federal Register** on February 7, 2013.[3] The Commission received two comment letters on the proposed rule change.[4] The Exchange submitted a response on March 14, 2013.[5] On March 19, 2013, the Commission extended the time period for Commission action.[6] This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange is proposing to (1) to adopt a new order type called the ''Auto-Ex Only'' order; and (2) add new definitions for ''Auto-Ex Mode'' and ''Auto-Ex Order'' to clarify the operation of its existing Auto-Ex Mode of order interaction.

A. Auto-Ex Only Order Type

NSX is a price-time priority market with two modes of order interaction: (1) Auto-Ex Mode and (2) Order Delivery Mode.[7] The Exchange's trading system, NSX BLADE® (''Blade''), matches and executes like-priced orders, regardless of whether an order was entered via Auto-Ex Mode or Order Delivery Mode, that are resting on the NSX Book [8] in accordance with the process described in NSX Rule 11.13(b)(1).

Currently, an incoming marketable order would be executed immediately against contra-side orders entered via Auto-Ex Mode resting in the NSX Book. However, that same incoming marketable order may experience a delay if matched against an order resting on the NSX Book that was entered via Order Delivery Mode.[9] To provide Users [10] with the ability to avoid the delays associated with order delivery service, the Exchange proposes to implement a new order type—the Auto-Ex Only order, which would allow Users to submit an immediate-or-cancel (''IOC'') limit [11] or market order with ''Auto-Ex Only'' handling instructions.[12] Auto-Ex Only orders would be executed solely against orders with price-time priority entered via Auto-Ex Mode and posted to the NSX Book. An Auto-Ex Only order would not interact with any orders resting on the NSX Book entered via Order Delivery Mode and would not be routed away to another trading center. Like an IOC order, the unexecuted portion of an Auto-Ex Only order would be cancelled if not fully matched for execution against Auto-Ex orders with price/time priority on the NSX Book.

According to the Exchange, its price/time priority and order execution rules [13] would limit an Auto-Ex Only order's ability to interact with certain undisplayed orders. Specifically, an Auto-Ex Only order would first execute against displayed orders on the NSX Book. An Auto-Ex Only order could be precluded from interacting with an undisplayed order (*e.g.,* a Zero Display Reserve Order [14]) entered via Auto-Ex Mode if the undisplayed order shares a price point with an order entered via Order Delivery Mode. Similarly, an order entered via Order Delivery Mode could also prevent an incoming Auto-Ex Only order from interacting with the undisplayed portion of a Reserve Order [15] under circumstances in which the order entered via Order Delivery Mode has price/time priority. Like displayed orders, the displayed portion of a Reserve Order will interact against incoming Auto-Ex Only orders only to the extent that there are no orders entered via Order Delivery Mode in the NSX Book with price/time priority.[16]

B. Proposed New Definitions

The Exchange proposes to amend NSX Rules 1.5 and 11.11 to include definitions for Auto-Ex Mode and Auto-Ex orders. Specifically, the Exchange proposes to define ''Automatic Execution Mode'' as ''[t]he mode of order interaction on the Exchange as described in Rule 11.13(b)(1).'' [17] In addition, the Exchange proposes to define an ''Auto-Ex Order'' as ''[a] limit or market order that is automatically executed by the System against any marketable contra side order as in the manner described in Rule 11.13(b)(1).'' [18] These definitions are intended to add clarity and provide the ability to internally cross reference these terms in the Exchange's rules.

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 68807 (Feb. 1, 2013), 78 FR 9094 (Feb. 7, 2013) (''Notice'').

[4] *See* Letters to Elizabeth M. Murphy, Secretary, Commission, from Peter J. Driscoll, Investment Professional, dated February 14, 2013 (''Driscoll Letter'') and Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated Mar. 6, 2013 (''SIFMA Letter'').

[5] *See* Letter to Elizabeth M. Murphy, Secretary, Commission, from Christopher Solgan, Senior Regulatory Counsel, NSX, dated Mar. 14, 2013 (''NSX Response'').

[6] *See* Securities Exchange Act Release No. 69183 (Mar. 19, 2013), 78 FR 18377 (Mar. 26, 2013).

[7] *See* Securities Exchange Act Release No. 54391 (Aug. 31, 2006), 71 FR 52836 (Sept. 7, 2006) (SR–NSX–2006–08). The Exchange's two modes of order interaction are described in NSX Rule 11.13(b).

[8] ''NSX Book'' is defined as ''the System's electronic file of orders.'' *See* NSX Rule 1.5(N)(1).

[9] The delays are due to the Exchange sending to and receiving a response from a User that has satisfied the Exchange's requirements to participate in order delivery service. *See* NSX Rule 11.13(b)(2) and the Interpretations and Policies thereto. To be eligible for order delivery service, Users must demonstrate to Exchange examiners that the User's system can automatically process the inbound order and respond immediately.

[10] A ''User'' is any ETP Holder or Sponsored Participant who is authorized to obtain access to the System pursuant to NSX Rule 11.9. *See* NSX Rule 1.5(U)(1).

[11] An IOC order is a limit order that is to be executed in whole or in part as soon as such order is received, and the portion not so executed is to be treated as cancelled. *See* NSX Rule 11.11(b)(1). An order designated as IOC is not eligible to be routed away pursuant to NSX Rule 11.15.

[12] *See* Proposed NSX Rule 11.11(c)(13).

[13] *See* NSX Rule 11.14(a) and, with respect to Reserve Orders (including Zero Display Reserve Orders), NSX Rule 11.14(a)(4).

[14] *See* NSX Rule 11.11(c)(2)(A). A User may enter a Reserve Order with zero display quantity, in which case the Reserve Order will be known as a ''Zero Display Reserve Order.''

[15] A Reserve Order is defined as a ''limit order with a portion of the quantity displayed and with a reserve portion of the quantity that is not displayed.'' *See* NSX Rule 11.11(c)(2).

[16] The Exchange provided several illustrative examples that provide greater clarity regarding how the proposed Auto-Ex Only order type will interact with other orders. *See* Notice, *supra* note 3, at 9096–7.

[17] *See* Proposed NSX Rule 1.5(A)(3). Rule 11.13(b)(1) provides as follows: ''If automatic execution is selected, the System shall match and execute like-priced orders on an order by order basis only at the specific instruction of Users.''

[18] *See* Proposed NSX Rule 11.11(c)(11). Rule 11.13(b)(1) provides as follows: ''If automatic execution is selected, the System shall match and execute like-priced orders on an order by order basis only at the specific instruction of Users.''

Section 6 of the Act [19] and the rules and regulations thereunder applicable to a national securities exchange.[20] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[21] which requires, among other things, that the Exchange's rules be 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 Commission believes that NSX's proposed new order type will offer Users the option of interacting with marketable orders on the NSX's Book without having to incur the delays associated with the order delivery service. Accordingly, the Commission finds that the proposed rule change is consistent with the Act as it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market, and protects investors and the public interest. The Commission further believes that NSX's proposed new definitions will provide clarity when referring to the Auto-Ex Mode of order interaction and the Auto-Ex order type, which will further the Act's goal of promoting just and equitable principles of trade.

The Commission received two comment letters on the proposed rule change. Both commenters asserted that the proposed order type raises concerns under Regulation NMS.[22] Specifically, one commenter stated that the proposed Auto-Ex Only order is inconsistent with the underlying policy goals of Rule 611 of Regulation NMS (''Order Protection Rule'') [23] by designating that only certain ''protected quotations'' are in fact protected.[24] NSX responded to this concern by explaining that the proposed Auto-Ex Only order would not trade-through a protected quotation established by an order submitted via Order Delivery Mode.[25] According to the Exchange, Blade would reject any Auto-Ex Only order when there is an order that was entered via Order Delivery Mode that has price/time priority resting on the NSX Book. Based on the Exchange's representations, the Commission does not believe that the Auto-Ex Only order is inconsistent with Rule 611 of Regulation NMS because an Auto-Ex Only order will not trade-through a protected quotation in violation of Rule 611.

In addition, one of the commenters stated that the proposed new order type is inconsistent with Rule 610(a) of Regulation NMS (''Access to Quotations Rule''),[26] which prohibits an exchange from imposing discriminatory terms that prevent or inhibit any person from obtaining efficient access to such quotations, by preventing orders submitted through Order Delivery Mode from interacting with Auto-Ex Only orders.[27] NSX responded to this commenter's concern by stating that the Auto-Ex Only order would not prevent or inhibit any person from obtaining access to a displayed quotation.[28] The Exchange further explained that Users could access a displayed quotation by submitting an intermarket sweep order or by submitting an Auto-Ex Only order to gain access to orders in the Exchange's displayed quotations that are entered using the Auto-Ex Mode.[29] The Commission does not believe that the Auto-Ex Only order is inconsistent with the Access to Quotations Rule because it does not prevent or inhibit a market participant from gaining access to a displayed quotation.

Both commenters also noted concerns regarding the complexity of the U.S. equity market structure, and one commenter stated that the NSX's proposal would unnecessarily continue the trend of complexity for its sake, without justification as to how the proposal would serve the larger investing public.[30] The same commenter believes that the NSX's proposal adds to the proliferation of order types, with the potential to cause investor confusion without serving any identifiable policy objective other than to allow market participants to bypass quotations that are otherwise entitled to trade-through protection under Regulation NMS simply because of the manner in which the quotations were entered.[31] The other commenter asserted that the proposed order type adds another layer of complexity to an already overly complex market structure.[32] The Commission believes that the NSX's proposed Auto-Ex Only order will benefit Users by offering them the option of interacting with marketable orders on the NSX's Book without having to incur the delays associated with the order delivery service and will not cause investor confusion or significantly add to the complexity of the existing market structure.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[33] that the proposed rule change (SR–NSX–2013–02) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11172 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78f.

[20] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78f(b)(5).

[22] *See* SIFMA Letter and Driscoll Letter, *supra* note 4.

[23] 17 CFR 242.611. Rule 611(a)(1) requires trading centers to, among other things, establish, maintain, and enforce written policies and procedures that are reasonably designed to prevent trade-throughs on that trading center of protected quotations in NMS stocks.

[24] *See* SIFMA Letter, *supra* note 4, at 2.

[25] *See* NSX Response, *supra* note 5, at 2.

[26] 17 CFR 242.610(a).

[27] *See* SIFMA Letter, *supra* note 4, at 2–3.

[28] *See* NSX Response, *supra* note 5, at 2.

[29] *See id.*

[30] *See* Driscoll Letter, *supra* note 4, at 1–2 and SIFMA Letter, *supra* note 4, at 3.

[31] *See* SIFMA Letter, *supra* note 4, at 3.

[32] *See* Driscoll Letter, *supra* note 4, at 2. The commenter went on to question whether the current market structure needs an order delivery function and whether the current criteria under which order delivery operates is appropriate. *Id.* at 2–4. This concern is beyond the scope of the proposed rule change and the Commission's consideration of such proposed rule change.

[33] 15 U.S.C. 78s(b)(2).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69518; File No. SR–MIAX–2013–18]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Priority Customer Size

May 6, 2013.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 24, 2013, Miami International Securities Exchange LLC (''MIAX'' or ''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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 filing a proposal to amend Exchange Rule 506, Collection and Dissemination of Quotations, by adopting new Exchange Rule 506(c)(ii) to state that the Exchange will make available to subscribers of its MIAX Top of Market (''ToM'') data feed the quantity of Priority Customer (defined below) contracts included in the MIAX Best Bids and Offers (''MBBOs'') disseminated by the Exchange.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX'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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make available to subscribers of its ToM market data product [3] the quantity of Priority Customer (defined below) contracts included in the MBBO disseminated by the Exchange in order to provide additional transparency to ToM subscribers regarding the disseminated MBBO. The Exchange does not intend to charge additional fees for the inclusion of Priority Customer size in the aggregate size component of ToM at this time.

Currently, the ToM is a direct data feed that includes: the Exchange's best bid and offer, with aggregate size and last sale information on the MIAX system; opening imbalance condition information; opening and intra-day routing information; Expanded Quote Range information; Post-Halt Notification; and Liquidity Refresh condition information.[4] The ToM data feed includes data that is identical to the data sent to the processor for the Options Price Reporting Authority (''OPRA''). The ToM and OPRA data leave the MIAX system at the same time, as required under Section 5.2(c)(iii)(B) of the Limited Liability Company Agreement of the Options Price Reporting Authority LLC (the ''OPRA Plan''), which prohibits the dissemination of proprietary information on any more timely basis than the same information is furnished to the OPRA System for inclusion in OPRA's consolidated dissemination of options information.

The Exchange now proposes to make available additional information in the ToM data feed that specifies the quantity of Priority Customer [5] contracts that are included in the aggregate size of the MBBO. Information regarding the quantity of Priority Customer interest included in the size of the MBBO may provide market participants transparency as to how orders would be allocated when the Priority Customer Overlay [6] is in effect. When the Priority Customer Overlay is in effect, Priority Customer Orders on the Exchange generally have priority over Professional Interest and all Market Maker interest at the same price. The Exchange believes that the additional information regarding the quantity of Priority Customers contracts may provide certain ToM subscribers an additional tool to use when making routing, quotation, price and size decisions regarding where they should send orders and quotes, and the nature of such orders and quotes (*i.e.,* price and size).

As stated above, the Exchange is not proposing at this time to assess additional fees for the inclusion of Priority Customer size as a component of the information included in the ToM market data product. The Exchange notes that it would file a 19b–4 Rule Filing prior to assessing additional fees for the Priority Customer size component of the information included in the ToM market data product.

Because of the technology changes associated with this rule proposal, the Exchange will announce the implementation date of the proposal in an Exchange Circular to be published no later than 30 days after the publication of the notice in the **Federal Register**. The implementation date will be no later than 30 days following publication of the Exchange Circular announcing publication of the notice in the **Federal Register**.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) [7] of the Act in general, and furthers the objectives of Section 6(b)(5) [8] of the Act 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest, and it is not designed to permit unfair discrimination among customers, brokers, or dealers.

The addition of Priority Customer size as a component of the information included in the ToM product is designed to promote just and equitable principles of trade by providing ToM subscribers with market data that should enable them to make informed decisions on trading in MIAX options by using the ToM data to assess current market conditions that directly affect such decisions. The proposal removes impediments to, and is designed to further perfect, the mechanisms of a free and open market and a national market system by making the MIAX market more transparent and accessible to market participants making routing decisions concerning their options orders, and concerning the nature of their quotes.

The ToM market data product is also designed to protect investors and the public interest by providing market data to subscribers that offers market participants additional information in

[3] *See* Securities Exchange Act Release No. 69007 (February 28, 2013), 78 FR 14617 (March 6, 2013) (SR–MIAX–2013–05).

[4] *See id.*

[5] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). *See* Exchange Rule 100.

[6] The Exchange generally uses a pro-rata allocation model, and deploys certain ''Priority Overlays'' on a class-by-class basis. One such Priority Overlay is the Priority Customer Overlay. When the Priority Customer Overlay is in effect, the highest bid and lowest offer have priority except that Priority Customer Orders have priority over Professional Interest and all Market Maker interest at the same price. If there are two or more Priority Customer Orders for the same options series at the same price, priority is afforded to such Priority Customer Orders in the sequence in which they are received by the System. *See* Exchange Rule 514(d)(1).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

order to make decisions concerning their orders and/or quotes.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

MIAX operates within a highly competitive market in which market participants can readily send order flow to other competing venues if, among other things, they deem allocation rules at a particular venue to be unreasonable or disproportionate. The proposed rule change is intended to offer market participants additional information and transparency in the marketplace, and therefore enhances competition among exchanges by further enabling market participants to make informed order routing and quoting decisions.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) [10] 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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–MIAX–2013–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2013–18. 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 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–MIAX–2013–18 and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11141 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69522; File No. SR–BX–2013–034]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Its Schedule of Fees and Rebates for Execution of Orders for Securities Priced at $1 or More Under Rule 7018

May 6, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 30, 2013, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes changes to its schedule of fees and rebates for execution of orders for securities priced at $1 or more under Rule 7018. While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on May 1, 2013. The text of the proposed rule change is also available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing minor adjustments to the fees that it charges members for executed orders that provide liquidity through the NASDAQ OMX BX Equities System.[3] Currently, BX charges $0.0018 per share executed for displayed orders that provide liquidity unless a more favorable rate applies.[4] Effective May 1, 2013, BX proposes to increase this fee to $0.0020 per share executed. BX will, however, continue to charge the $0.0018 per share executed fee for a displayed order that provides liquidity if entered through a BX MPID through which the member provides an average daily volume of 4 million or more shares of liquidity during the month.

2. Statutory Basis

BX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which BX operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The change to introduce a volume requirement with respect to the current $0.0018 per share executed rate for displayed orders that provide liquidity, and the increase in the applicable rate for displayed orders that do not meet the volume requirement, is reasonable because the applicable increase is only $0.0002 per share executed, and the volume requirement associated with maintaining the existing fee is a modest 4 million shares per day, or 0.067% of total consolidated volume on a trading day with total consolidated volume of 6 billion shares. Moreover, the Exchange continues to offer an even more favorable charge to members using midpoint pegged orders, which may be used by all members, regardless of volume. The change is consistent with an equitable allocation of fees because it is consistent with the established practice at a number of national securities exchanges of providing more favorable fee economics to members that contribute to market quality and the Exchange's market share by achieving certain volume requirements. In this instance, the Exchange's practice of paying a credit to members accessing liquidity gives liquidity providers a greater assurance of speedy execution. A member that provides a comparatively large volume of liquidity is demonstrating its commitment to the viability of BX's market model by posting orders at prices that attract members seeking liquidity. Accordingly, BX believes that it is equitable for the fees charged to such a member to be more favorable than the fees charged to members providing lower volumes of liquidity. The Exchange further believes that the change is not unfairly discriminatory because the associated volume requirements are not very high and because the Exchange provides an alternative means of paying a lower fee for orders that provide liquidity.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX 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. BX notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, BX must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, BX believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In this instance, although the proposed change imposes a volume condition on the availability of a fee of $0.0018 per share executed for displayed orders that provide liquidity and raises the fee for members not meeting the volume condition, the volume condition is not markedly high and the fee increase is only $0.0002. Moreover, if the changes are unattractive to market participants, it is likely that BX will lose market share as a result. Accordingly, BX does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and paragraph (f) of Rule 19b–4 thereunder.[8]

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–BX–2013–034 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission,

[3] Like the EDGA Exchange and the BATS–Y Exchange, BX charges for execution of orders that provide liquidity and provides a credit for execution of orders that access liquidity.

[4] Specifically, the applicable charge is $0.0015 per share executed for a member entering an order through a market participant identifier (''MPID'') that is eligible for the Exchange's Qualified Liquidity Provider program. A member seeking to qualify an MPID for the program must achieve certain requirements pertaining to volume and time at the national best bid/best offer (''NBBO''), as specified in Rule 7018. BX also charges $0.0015 per share executed for midpoint pegged orders that provide liquidity, but charges $0.0025 per share executed for other non-displayed orders that provide liquidity.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f).

100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2013–034. 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 BX. 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–BX–2013–034, and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11173 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69521; File No. SR–NASDAQ–2013–071]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend NASDAQ Rule 4763

May 6, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4[2] thereunder, notice is hereby given that on April 24, 2013, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to amend NASDAQ Rule 4763 (Short Sale Price Test Pursuant to Rule 201 of Regulation SHO) to establish that the short sale price test for NASDAQ-listed securities will not be calculated until after NASDAQ completes the Nasdaq Opening Cross or, where no Nasdaq Opening Cross occurs, begins trading pursuant to NASDAQ Rule 4752.

The text of the proposed rule change is below.[3] Proposed new language is italicized; deletions are bracketed.

* * * * *

4763. Short Sale Price Test Pursuant to Rule 201 of Regulation SHO

(a)–(b) No change.

(c) Determination of Trigger Price. For covered securities for which the Exchange is the listing market, the System shall determine whether a transaction in a covered security has occurred at a Trigger Price and shall immediately notify the single plan processor.

(1) The System will not calculate the Trigger Price of a covered security until*:* [it opens trading for that security.]

(A) after the completion of the Nasdaq Opening Cross pursuant to Rule 4752(d), for securities in which a Nasdaq Opening Cross occurs, or

(B) after the System begins trading pursuant to Rule 4752(c) for securities in which no Nasdaq Opening Cross occurs.

(2) No change.

(d)–(g) No change.

* * * * *

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. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[3] Changes are marked to the rule text that appears in the electronic manual of Nasdaq found at *http://nasdaq.cchwallstreet.com.*

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 201 of Regulation SHO [4] contains a short sale-related circuit breaker that, if triggered, imposes a restriction on the prices at which securities may be sold short (''short sale price test''). Rule 201(b) requires that trading centers,[5] such as NASDAQ, establish, maintain, and enforce written policies and procedures reasonably designed to prevent the execution or display of a short sale order of a covered security [6] at a price that is less than or equal to the current national best bid [7] if the price of that covered security decreases by 10% or more from the covered security's closing price as determined by the listing market [8] for the covered security as of the end of regular trading hours [9] on the prior day (''Trigger

[4] 17 CFR 242.201. *See also* Securities Exchange Act Release No. 61595 (Feb. 26, 2010), 75 Fed. Reg. 11232 (Mar. 10, 2010) and Division of Trading and Markets: Responses to Frequently Asked Questions Concerning Rule 201 of Regulation SHO (''T&M FAQs'').

[5] Rule 201(a)(9) states that the term ''trading center'' shall have the same meaning as in Rule 600(b)(78) of Regulation NMS. Rule 600(b)(78) defines a ''trading center'' as ''a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent.'' 17 CFR 242.600(b)(78).

[6] The term ''covered security'' shall have the same meaning as in Rule 201 of Regulation SHO. Rule 201(a)(1) defines the term ''covered security'' to mean any ''NMS stock'' as defined under Rule 600(b)(47) of Regulation NMS. Rule 600(b)(47) of Regulation NMS defines an ''NMS stock'' as ''any NMS security other than an option.'' Rule 600(b)(46) of Regulation NMS defines an ''NMS security'' as ''any security or class of securities for which transaction reports are collected, processed, and made available pursuant to an effective transaction reporting plan, or an effective national market system plan for reporting transactions in listed options.'' 17 CFR 242.201(a)(1); 17 CFR 242.600(b)(47); and 17 CFR 242.600(b)(46).

[7] The term ''national best bid'' shall have the same meaning as in Rule 201 of Regulation SHO. Rule 201(a)(4) states that such term shall have the same meaning as in Rule 600(b)(42) of Regulation NMS. 17 CFR 242.201(a)(4). *See also* 17 CFR 242.600(b)(42).

[8] The term ''listing market'' shall have the same meaning as in Rule 201 of Regulation SHO. Rule 201(a)(3) defines the term ''listing market'' to have the same meaning as the term ''listing market'' as defined in the effective transaction reporting plan for the covered security. 17 CFR 242.201(a)(3). *See also* 17 CFR 242.201(a)(2).

[9] ''Regular trading hours'' is defined in Rule 201 to have the same meaning as in Rule 600(b)(64) of Regulation NMS. *See* Rule 201(a)(7). Rule

Price''). Rule 4763(b) provides, in compliance with Rule 201, that in the event the short sale price test is triggered, the Exchange will not execute or display a short sale order with respect to a covered security at a price that is less than or equal to the current national best bid.

Under Rule 4763(c), where NASDAQ is the listing market for a covered security, the System (as defined in NASDAQ Rule 4751(a)) will determine whether the short sale price test of Rule 201 has been triggered (*i.e.,* whether a transaction in a covered security has occurred at a Trigger Price) and will immediately notify the single plan processor for the covered security. Currently under Rule 4763(c)(1), the System will not calculate the Trigger Price of a covered security until the Exchange opens trading for that security. Because the phrase ''opens trading'' is not defined in NASDAQ's rules, some ambiguity exists regarding its precise application. The purpose of the proposed rule change is to clearly establish when NASDAQ will begin calculating whether the short sale price test of Rule 201 of Regulation SHO under the Act has been triggered for NASDAQ-listed securities.

Specifically, NASDAQ members have questioned whether the short sale price test can be triggered in a NASDAQ-listed security by an execution on an away market that occurs after 9:30:00 a.m. but before NASDAQ completes the Nasdaq Opening Cross pursuant to Rule 4752. Typically, NASDAQ systems require less than 2 seconds to complete all Nasdaq Opening Crosses in NASDAQ-listed securities. Therefore, this question applies only to the limited circumstances in which an away market prints a regular way execution which would trigger the short sale price test of Rule 201 under Regulation SHO during the brief period after 9:30:00 but prior to the Nasdaq Opening Cross.

Accordingly, NASDAQ is modifying Rule 4763(c)(1) to state specifically when NASDAQ will begin calculating whether a transaction in a covered security has occurred at a Trigger Price. For securities in which a Nasdaq Opening Cross occurs as described in Rule 4752(d), NASDAQ will begin calculating the short sale price test after completing the Nasdaq Opening Cross. For securities in which no Nasdaq Opening Cross occurs, as described in Rule 4752(c), NASDAQ will begin calculating the short sale price test immediately when the System begins regular way trading pursuant to Rule 4752(c). NASDAQ believes that this proposed change eliminates any ambiguity that exists in the current rule.[10]

2. Statutory Basis

NASDAQ believes that its proposal is consistent with Section 6(b) of the Act[11] in general, and furthers the objectives of Section 6(b)(5) of the Act[12] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Specifically, NASDAQ believes that it is important to resolve ambiguity in NASDAQ's rules, particularly a rule that NASDAQ administers as a listing market and that impacts all trading in a given security. The proposed change will enhance the fairness and efficiency of the NASDAQ market without affecting market participants' ability or cost to comply with applicable regulatory requirements.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ 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. NASDAQ does not believe that competition exists regarding when an exchange begins calculating the short sale price test. However, to the extent such competition exists today, the proposed rule change conforms to the current practice of the New York Stock Exchange (''NYSE'') and, therefore, equalizes the two markets' competitive positions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A) of the Act[13] and paragraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay because the proposed rule change provides more clarity regarding the application of Regulation SHO under the Act and resolves an ambiguity in the Exchange's rules. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[15] Waiver of the operative delay will allow the Exchange to resolve a potential ambiguity in NASDAQ's rules. For these reasons, the Commission designates the proposed rule change as operative upon filing.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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:

600(b)(64) provides that ''Regular trading hours means the time between 9:30 a.m. and 4:00 p.m. Eastern Time, or such other time as is set forth in the procedures established pursuant to § 242.605(a)(2).'' 17 CFR 242.600(b)(64). *See also* T&M FAQs 1.1 and 1.2.

[10] The proposed rule does not affect market participants' obligations contained in Regulation SHO under the Act. *See* 17 CFR 242.200 *et seq.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6(iii) requires a self-regulatory organization to provide the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–2013–071 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2013–071. 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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; 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–2013–071 and should be submitted on or before May 31, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–11145 Filed 5–9–13; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Order of Suspension of Trading in the Matter of CoreCare Systems, Inc., Forticell Bioscience, Inc., Michelex Corporation, and Rx for Africa, Inc.

May 8, 2013.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of CoreCare Systems, Inc. because it has not filed any periodic reports since the period ended June 30, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Forticell Bioscience, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Michelex Corporation because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Rx for Africa, Inc. because it has not filed any periodic reports since the period ended March 31, 2007.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies. Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on May 8, 2013, through 11:59 p.m. EDT on May 21, 2013.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2013–11238 Filed 5–8–13; 4:15 pm]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 13559 and # 13560]

Texas Disaster # TX–00401

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Texas dated May 2, 2013.

Incident: West Fertilizer Plant Explosion.

Incident Period: 04/17/2013.

Effective Date: 05/02/2013.

Physical Loan Application Deadline Date: 07/01/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 02/03/2014.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Mclennan.

Contiguous Counties: Texas:

Bell; Bosque; Coryell; Falls; Hill; Limestone.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.375
Homeowners Without Credit Available Elsewhere	1.688
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 135594 and for economic injury is 135600.

The State which received an EIDL Declaration # is TEXAS.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: May 2, 2013

Karen G. Mills,

Administrator.

[FR Doc. 2013–11121 Filed 5–9–13; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 8316]

30-Day Notice of Proposed Information Collection: Evacuee Manifest and Promissory Note

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. 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 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to June 10, 2013.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

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 A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/L), U.S. Department of State, SA–29, 4th Floor, Washington, DC 20520 or at *CA-OCS-L@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Evacuee Manifest and Promissory Note.
- *OMB Control Number:* 1405–XXXX.
- *Type of Request:* New.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS–5528.
- *Respondents:* U.S. citizens applying for emergency loan assistance during an evacuation.
- *Estimated Number of Respondents:* 790.
- *Estimated Number of Responses:* 790.
- *Average Hours Per Response:* 20 minutes.
- *Total Estimated Burden:* 263 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain Benefits.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The purpose of the DS–5528 is to document the evacuation of persons from abroad when their lives are endangered by war, civil unrest, or natural disaster, document issuance of a crisis evacuation loan, to obtain a Privacy Act waiver to share information about the welfare of a citizen or lawful permanent resident with authorized, designated persons, and to facilitate debt collection. 22 U.S.C. 4802(b) is one of the primary statutes that make the use of the DS–5528 legal.

Methodology

An electronic version of the Evacuee Manifest and Promissory Note will be created to allow applicants to submit their loan requests to the Bureau of Consular Affairs and our embassies and consulates abroad. Once the applicant has entered the information and submitted the form, the information will be made available to consular officers via the Department of State network and systems for further processing.

Dated: April 10, 2013.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Overseas Citizen Services, Department of State.

[FR Doc. 2013–11178 Filed 5–9–13; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 8317]

30-Day Notice of Proposed Information Collection: Repatriation/Emergency Medical and Dietary Assistance Loan Application

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. 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 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to June 10, 2013.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

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 A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/L), U.S. Department of State, SA–29, 4th Floor, Washington, DC 20520 or at *CA-OCS-L@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Repatriation/Emergency Medical and Dietary Assistance Loan Application.
- *OMB Control Number:* 1405–0150.
- *Type of Request:* Revised.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).

- *Form Number:* DS–3072.
- *Respondents:* U.S. Citizens applying for emergency loan assistance.
- *Estimated Number of Respondents:* 1,357.
- *Estimated Number of Responses:* 1,357.
- *Average Hours per Response:* 20 minutes.
- *Total Estimated Burden:* 452 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain Benefits.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The principal purpose of the information gathered is to provide an accurate list of U.S. citizens and non-U.S. citizens receiving repatriation/emergency medical and dietary assistance in foreign countries. The information collected will be used to process the emergency loan, facilitate reception and resettlement assistance in the United States and for debt collection. Respondents are private U.S. citizens and their dependents abroad who are destitute and in need of repatriation to the United States and/or emergency medical and dietary assistance. 22 U.S.C. 2670(j) is one of the primary statutes that make the use of the DS–3072 legal.

Methodology: The Bureau of Consular Affairs will post this form on Department of State Web sites to give respondents the opportunity to complete the form online, or print the form and fill it out manually and submit the form in person or by fax or mail.

Dated: April 10, 2013.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Overseas Citizen Services, Department of State.

[FR Doc. 2013–11179 Filed 5–9–13; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 8318]

Culturally Significant Objects Imported for Exhibition Determinations: ''Shaping Power: Luba Masterworks From the Royal Museum for Central Africa''

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), Executive Order 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, and 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 ''Shaping Power: Luba Masterworks from the Royal Museum for Central Africa,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Los Angeles County Museum of Art, Los Angeles, California, from on or about July 7, 2013, until on or about January 5, 2014, 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 exhibit objects, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6469). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: May 3, 2013.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–11180 Filed 5–9–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8319]

Culturally Significant Objects Imported for Exhibition Determinations: ''Impressionists on the Water''

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), Executive Order 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 ''Impressionists on the Water,'' 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 Fine Arts Museums of San Francisco, San Francisco, CA, from on or about June 1, 2013, until on or about October 13, 2013; the Peabody Essex Museum, Salem, MA, from on or about November 9, 2013, until on or about February 17, 2014, 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 exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: May 6, 2013.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–11181 Filed 5–9–13; 8:45 am]

BILLING CODE 4710–05–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: March 1 through March 31, 2013.

ADDRESSES: Susquehanna River Basin Commission, 1721 North Front Street, Harrisburg, PA 17102–2391.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, telephone: (717) 238–0423, ext. 306; fax: (717) 238–2436; email: *rcairo@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Approvals By Rule Issued Under 18 CFR 806.22(f)

1. Chief Oil & Gas LLC, Pad ID: J. Brown Drilling Pad, ABR–201303001, Troy Township, Bradford County, Pa.; Consumptive Use of Up to 2.000 mgd; Approval Date: March 12, 2013.
2. Carrizo Marcellus, LLC, Pad ID: Tomkins, ABR–201303002, McNett Township, Lycoming County, Pa.; Consumptive Use of Up to 2.100 mgd; Approval Date: March 15, 2013.
3. Carrizo Marcellus, LLC, Pad ID: Hanlon, ABR–201303003, McNett Township, Lycoming County, Pa.; Consumptive Use of Up to 2.100 mgd; Approval Date: March 15, 2013.
4. Carrizo Marcellus, LLC, Pad ID: Baumunk Lake South, ABR–201303004, Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 2.100 mgd; Approval Date: March 15, 2013.
5. Carrizo Marcellus, LLC, Pad ID: Baumunk Lake North, ABR–201303005, Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 2.100 mgd; Approval Date: March 15, 2013.
6. Southwestern Energy Production Company, Pad ID: DRANN PAD, ABR–201303006, New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: March 15, 2013.
7. Cabot Oil & Gas Corporation, Pad ID: MolnarM P1, ABR–201303007, Brooklyn Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 15, 2013.
8. Chesapeake Appalachia, LLC, Pad ID: Jes, ABR–201303008, Wilmot Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 15, 2013.
9. Chesapeake Appalachia, LLC, Pad ID: Lightcap, ABR–201303009, Overton and Elkland Townships, Bradford and Sullivan Counties, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 15, 2013.
10. Chesapeake Appalachia, LLC, Pad ID: Lasher, ABR–201303010, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 15, 2013.
11. Cabot Oil & Gas Corporation, Pad ID: CastrogiovanniA P3, ABR–201303011, Bridgewater Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 29, 2013.
12. Southwestern Energy Production Company, Pad ID: Marichini-Zingieser (Pad 9), ABR–201303012, Herrick Township, Bradford County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: March 29, 2013.
13. Chesapeake Appalachia, LLC, Pad ID: Virginia, ABR–201303013, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 29, 2013.
14. Cabot Oil & Gas Corporation, Pad ID: CarpenettiR P1, ABR–201303014, Lathrop Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 29, 2013.

Authority: Pub. L. 91–575, 84 Stat. 1509 et seq., 18 CFR parts 806, 807, and 808.

Dated: April 30, 2013.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2013–11160 Filed 5–9–13; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Rescinded for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the approved by rule projects rescinded by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: March 1 through March 31, 2013.

ADDRESSES: Susquehanna River Basin Commission, 1721 North Front Street, Harrisburg, PA 17102–2391.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, telephone: (717) 238–0423, ext. 306; fax: (717) 238–2436; email: *rcairo@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, being rescinded for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(e) and 806.22(f) for the time period specified above:

Rescinded ABR Issued March 1–31, 2013

1. Norse Energy Corp USA, Pad ID: Aarismaa #1, ABR–20100666, Preston Town, Chenango County, NY; Rescind Date: March 18, 2013.
2. Norse Energy Corp USA, Pad ID: Anderson, C. #1, ABR–201007111, Coventry Town, Chenango County, NY; Rescind Date: March 18, 2013.
3. Norse Energy Corp USA, Pad ID: Byler, R. #1, ABR–20100627, Lebanon Town, Madison County, NY; Rescind Date: March 18, 2013.
4. Norse Energy Corp USA, Pad ID: Klecha, M. #1, ABR–201007108, Coventry Town, Chenango County, NY; Rescind Date: March 18, 2013.
5. Norse Energy Corp USA, Pad ID: Knapp, J. #1, ABR–201007107, Colesville Town, Broome County, NY; Rescind Date: March 18, 2013.
6. Norse Energy Corp USA, Pad ID: Krawiec #2, ABR–20100624, Smyrna Town, Chenango County, NY; Rescind Date: March 18, 2013.
7. Norse Energy Corp USA, Pad ID: Norse East #1, ABR–201007109, Afton Town, Chenango County, NY; Rescind Date: March 18, 2013.
8. Norse Energy Corp USA, Pad ID: Norse West #1, ABR–201007110, Afton Town, Chenango County, NY; Rescind Date: March 18, 2013.
9. Norse Energy Corp USA, Pad ID: Norse #3, ABR–201007112, Colesville Town, Broome County, NY; Rescind Date: March 18, 2013.
10. Norse Energy Corp USA, Pad ID: Stone #1, ABR–201007131, Coventry Town, Chenango County, NY; Rescind Date: March 18, 2013.
11. Norse Energy Corp USA, Pad ID: Thornhill #1, ABR–201007087, Colesville Town, Broome County, NY; Rescind Date: March 18, 2013.

Authority: Pub. L. 91–575, 84 Stat. 1509 et seq., 18 CFR parts 806, 807, and 808.

Dated: April 30, 2013.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2013–11136 Filed 5–9–13; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of New Approval of Information Collection: Aircraft Situational Display to Industry (ASDI) Block Requests

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for a new information collection. A **Federal Register** Notice for proposed process for limiting aircraft data displayed via ASDI, with a 60-day comment period soliciting comments on the following collection of information was published on May 9, 2012, vol. 77, no. 90, pages 27269–27271. The collected information will be used by the National Air Space Data Release Office to block aircraft flight data as requested by any interested aircraft owner or operator.

DATES: Written comments should be submitted by June 10, 2013.

FOR FURTHER INFORMATION CONTACT: Kathy DePaepe at (405) 954–9362, or by email at: *Kathy.A.DePaepe@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–XXXX.

Title: Aircraft Situational Display to Industry (ASDI) Block Requests.

Form Numbers: There are no FAA forms associated with this collection of information.

Type of Review: Clearance of a new information collection.

Background: A Policy Notice in the June 3, 2011 **Federal Register** (76 FR 32258) authorized the FAA to administer a program under which general aviation aircraft owners or operators and on-demand aircraft could have the ability to ''block'' their aircraft identification information from release into the ASDI data feed. H.R. 2112, the ''Consolidated and Further Continuing Appropriations Act, 2012'', and a December 16, 2011 **Federal Register** notice of interim policy (76 FR 78328) further expanded that authority to allow any interested aircraft owner or operator to simply opt out of the ASDI data feed, by submitting a written request to the FAA's ASDI Program Office.

Respondents: Approximately 6,000 owners and operators.

Frequency: One time per requesting owner/operator.

Estimated Average Burden per Response: 5 minutes.

Estimated Total Annual Burden: 500 hours.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to oira_submission@omb.eop.gov, or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on May 6, 2013.

Albert R. Spence,

FAA Assistant Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. 2013–11187 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Passenger Facility Charge (PFC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly Notice of PFC Approvals and Disapprovals. In August 2012, there were two applications approved. Additionally, nine approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: Charlottesville-Albemarle Airport Authority, Charlottesville, Virginia.

Application Number: 12–20–C–00–CHO.

Application Type: Impose and use a PFC.

PFC Level: $4.50.

Total PFC Revenue Approved In This Decision: $3,285,054.

Earliest Charge Effective Date: January 1, 2013.

Estimated Charge Expiration Date: July 1, 2016.

Class Of Air Carriers Not Required To Collect PFC'S: Air taxi/commercial operators filing or requested to file FAA From 1800–31.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Charlottesville Albemarle Airport.

Brief Description Of Projects Approved For Collection And Use:

Airfield lighting and vault.
Runway 21 extension—preliminary design.
Runway 21 extension—phase 1A.
Runway 21 extension—phase 1B offset localizer.
Runway 21 extension—phase 1B embankment.

Decision Date: August 6, 2012.

FOR FURTHER INFORMATION CONTACT: Jeffrey Breeden, Washington Airports District Office, (703) 661–1363.

Public Agency: Chattanooga Metropolitan Airport Authority, Chattanooga, Tennessee.

Application Number: 12–05–C–00–CHA.

Application Type: Impose and use a PFC.

Total PFC Revenue Approved In This Decision: $6,896,122.

PFC Level: $4.50.

Earliest Charge Effective Date: October 1, 2012.

Estimated Charge Expiration Date: June 1, 2017.

Class Of Air Carriers Not Required To COLLECT PFC'S: Air taxi/commercial operators filing FAA Form 1800–31 and operating at Chattanooga Metropolitan Airport (CHA).

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at CHA.

Brief Description Of Projects Approved For Collection And Use:

Terminal rehabilitation.
Wildlife assessment.
Solar farm—phase 1.
Computed Tomography—80 facility modification design and build-out.
Access control enhancements.
Security fence replacement.
Airfield pavement survey.
Jet bridge refurbishment.
Security checkpoint modification.
Friction measuring equipment.
Runway 20 resealing.
East public ramp expansion.
Terminal ramp rehabilitation.
North terminal ramp.
Preconditioned air and ground power units.
Runway protection zone land acquisition.
Police radios.
Police vehicle replacement.
Resurface west perimeter road.
Runway 2/20 edge light replacement.
Flight information displays.
Air stairs.
Replace airfield beacon.
PFC application development.
PFC program administration.

Brief Description of Project Partially Approved for Collection and Use:

Ground support equipment.

Determination: The lavatory and potable water carts do not meet the requirements of § 158.15(b).

Brief Description Of Withdrawn Projects:

Solar farm, phase 2.

5615 Lee Highway demolition.

Date Of Withdrawal: July 26, 2012.

Snow plow blade.

Date Of Withdrawal: August 6, 2012.

Decision Date: August 7, 2012.

FOR FURTHER INFORMATION CONTACT: Cynthia Wills, Memphis Airports District Office, (901) 322–8190.

AMENDMENTS TO PFC APPROVALS

Amendment No. city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimatd charge exp. date	Amended estimated charge exp. date
10–12–C–01–SLC Sal Lake City, UT	06/15/12	$70,253,000	$71,305,000	03/01/13	04/01/13
08–04–C–01–ABY Albany, GA	07/26/12	341,518	337,287	08/01/10	08/01/10
09–04–C–01–FAY Fayetteville, NC	08/08/12	3,796,330	1,992,908	06/01/14	10/01/12
98–01–C–01–CEC Crescent City, CA	08/13/12	58,330	53,752	06/01/00	06/01/00
06–05–C–02–PUW Pullman, WA	08/17/12	404,837	400,706	03/01/10	03/01/10
92–01–C–04–BNA Nashville, TN	08/20/12	99,443,100	96,350,366	08/01/99	08/01/99
08–05–C–02–MSL Muscle Shoals, AL	08/22/12	41,425	41,208	04/01/10	04/01/10
09–05–C–01–GUC Gunnison, CO	08/24/12	396,438	500,506	04/01/19	05/01/20
08–07–C–01–CLM Port Angeles, WA	08/24/12	191,838	36,129	10/01/11	10/01/11

Issued in Washington, DC, on May 2, 2013.

Joe Hebert,

Manager, Financial Analysis and Passenger Facility Charge Branch.

[FR Doc. 2013–11054 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment on Surplus Property Release at Tupelo Regional Airport, Tupelo, Mississippi

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on land release request.

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 Tupelo Airport Authority to waive the requirement that a 1.78-acre parcel of surplus property, located at the Tupelo Regional Airport, be used for aeronautical purposes.

DATES: Comments must be received on or before June 10, 2013.

ADDRESSES: Comments on this notice may be mailed or delivered in triplicate to the FAA at the following address: Jackson Airports District Office, 100 West Cross Street, Suite B, Jackson, MS 39208–2307.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Joshua Abramson, Executive Director Tupelo Airport Authority, at the following address: Mr. Joshua Abramson, Executive Director, Tupelo Airport Authority, 2704 W. Jackson Street, Tupelo, MS 38801–0306.

FOR FURTHER INFORMATION CONTACT: David Shumate, Program Manager, Jackson Airports District Office, 100 West Cross Street, Suite B, Jackson, MS 39208–2307, (601)664–9882. The land release request may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA is reviewing a request by Tupelo Airport Authority to release 1.78 acres of surplus property at the Tupelo Regional Airport. The property will be purchased by Rowan Oak Funds, LLC for a commercial retail business. The net proceeds from the sale of this property will be used for Airport Improvement Program eligible development.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the request, notice and other documents germane to the request in person at the Tupelo Regional Airport.

Issued in Jackson, Mississippi, on April 25, 2013.

Rans D. Black,

Manager, Jackson Airports District Office, Southern Region.

[FR Doc. 2013–10509 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on the Tappan Zee Hudson River Crossing Project in New York

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the U.S. Army Corps of Engineers (USACE) and U.S. Coast Guard (USCG).

SUMMARY: This notice announces actions taken by the USACE and USCG that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the Tappan Zee Hudson River Crossing (New NY Bridge) Project located in

Rockland and Westchester Counties, New York. Those actions grant permits and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before October 7, 2013. If this date falls on a Saturday, Sunday, or legal holiday, parties are advised to file their claim no later than the business day preceding this date. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Jonathan D. McDade, Division Administrator, Federal Highway Administration, Leo W. O'Brien Federal Building, Albany, New York 12207, Telephone (518) 431–4127; or Peter Sanderson, Project Director, New York State Thruway Authority, 555 White Plains Road, Tarrytown New York, 10591, Telephone (914) 524–5440.

SUPPLEMENTARY INFORMATION: On October 31, 2012, the FHWA published a ''Notice of Final Federal Agency Actions'' on the Tappan Zee Hudson River Crossing (New NY Bridge) Project in New York, in the **Federal Register** at FR Doc. 2012–26799. Tappan Zee Hudson River Crossing (New NY Bridge) Project is located on the Hudson River between the Village of South Nyack in Rockland County on the west and the Village of Tarrytown in Westchester County on the east. The bridge carries Interstate 87 (New York State Thruway) and Interstate 287. The Tappan Zee Hudson River (New NY Bridge) Project involves the replacement of the existing bridge with two new structures (one each for eastbound and westbound traffic), to the north of its existing location. Notice is hereby given that subsequent to the earlier FHWA notice, the USACE and USCG have taken final agency actions by issuing permits and approvals for the Tappan Zee Hudson River Crossing (New NY Bridge) Project in the State of New York. The actions by the USACE and the USCG, and the laws under which such actions were taken, are described in the permits and approvals received by each respective agency. The USACE issued their permit on April 25, 2013 (NAN–2012–00090), and the USCG issued their permit on April 13, 2013 (3–13–1). The documents are available by contacting the FHWA, the NYSDOT, or the NYSTA at the addresses provided above. The permits can be viewed and downloaded from the project Web site at *www.newnybridge.com.*

This notice applies to USACE and USCG agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351];
2. *Bridges:* General Bridge Act of 1946, 33 U.S.C. 525–533.
3. *Air:* Clean Air Act Section 176 (c), 42 U.S.C. 7506(c).
4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(g)], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712], Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 et seq.].
5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) et seq.]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].
6. *Wetlands and Water Resources:* Clean Water Act, 33 U.S.C. 1251–1377 (Section 319, 401, 404); Rivers and Harbors Act of 1899, 33 U.S.C. 401–406; Coastal Zone Management Act, 16 U.S.C. 1451–1465; Land and Water Conservation Fund (LWCF), 16 U.S.C. 4601–4604; Safe Drinking Water Act (SDWA), 42 U.S.C. 300(f)-300(j)(6); 33 U.S.C. 401–406; Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287.
7. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: May 2, 2013.

Jonathan D. McDade,

Division Administrator, Albany, NY.

[FR Doc. 2013–11138 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0041; Notice 2]

Fuji Heavy Industries USA, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of petition.

SUMMARY: Fuji Heavy Industries USA, Inc. (Fuji) has determined that certain model year 2010 Subaru Legacy passenger car and Outback multipurpose Passenger Cars, manufactured from the start of their 2010 model year production through June 30, 2009, did not comply with paragraph S19.2.2 of Federal Motor Vehicle Safety Standard FMVSS No. 208, *Occupant Crash Protection.* Fuji has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports,* dated July 16, 2009.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, Fuji has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of Fuji's petition was published, with a 30-day public comment period, on April 19, 2010, in the **Federal Register** (75 FR 20423). Comments were received from Advocates for Highway & Auto Safety. To view the petition, the comments, and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2010–0041.''

For further information on this decision, contact Mr. Lawrence Valvo, Office of Vehicle Safety Compliance, NHTSA, telephone (202) 366–5359.

Vehicles Involved: Affected are approximately 3,405 model year 2010 Subaru Legacy passenger car and Outback multipurpose Passenger Cars, manufactured from the start of their 2010 model year production through June 30, 2009. Fuji also estimated that 0.8% of those 3,405 have the subject noncompliance.

Summary of Fuji's Analysis and Arguments: Fuji explained that the noncompliance is that front passenger air bag suppression status telltale lamp did not illuminate as required by paragraph S19.2.2 of FMVSS No. 208.

Fuji expressed the belief that the cause of the noncompliance is an open circuit in the power supply to the lamp. The Company said that ''installation of the wiring harness to the multifunction display and passenger air bag suppression status telltale was routed at the instrument panel subsupplier such that tension was put on the wiring harness connector'' which can cause it to come loose. To correct this problem, the Company has re-routed the wiring harness to ''push'' rather than ''pull'' on the wiring harness connector in vehicles manufactured after July 10, 2009.

The noncompliance was discovered on July 1, 2009, at the Company's Subaru Indiana plant during a quality inspection process that revealed a number of multi-function displays that did not illuminate and further inspection revealed that this also affected the front passenger air bag suppression status telltale.[1]

On July 10, 2009, Fuji completed the inspection of 5,400 of its vehicles awaiting shipment and corrected the noncompliance of 45 vehicles by ''pushing tight'' the harness connector. In addition, Subaru of America, Inc. notified its U.S. dealers and distributors on July 16, 2009, and included complete repair instructions for vehicles in their inventory which had not been inspected or repaired prior to shipment from the Company.

Fuji believes that the noncompliance is inconsequential to motor vehicle safety. Fuji argues that:

> Based on the inspection of approximately 5,400 vehicles still at Subaru Automotive Indiana and a finding that the wiring harness connector to the front passenger air bag suppression status telltale or other multi-function display had been loose on 45 vehicles, Subaru has determined that the expected occurrence rate is about 0.8% [less than one percent].
>
> [Subaru] . . . has determined that 3,405 vehicles were shipped to dealers prior to the discovery of this problem. Using the above frequency rate, . . . [the Company] expect that only about 27 vehicles will have a noncompliance with FMVSS 208.
>
> All other aspects of the front passenger advanced air bag suppression system will continue to function properly.
>
> Since Subaru has both an OFF and ON indication in the suppression telltale, a complete absence of illumination is a warning that the lamp is not functioning. Since power to the telltale is also power to the multi-function display, the owner will have a clear indication to quickly report a problem to a Subaru dealer.
>
> Vibration bench testing in Japan by the [Company's] supplier revealed that no disengagement of a wiring harness connector that originally worked properly will occur during the use of vehicle.
>
> Dealers will receive a TSB with repair instructions on July 16, 2009 for any vehicles in their inventory, which had not been inspected or repaired prior to shipment to dealers or for vehicles where the owner reports a telltale/multi-function display problem. Dealers will also be instructed to check both the telltale and display at the first scheduled service (at 3,750 or 7,000 miles depending on variant).

In summary, Fuji/Subaru states that it believes the noncompliance is inconsequential to motor vehicle safety because the expected occurrence rate for the noncompliance is less than one percent (about 0.8%); a complete absence of illumination on the telltale gives a clear indication to the vehicle owner to quickly report a problem to the Subaru dealer; the Company's vibration testing supports the conclusion that this noncompliance is not likely to later occur in vehicles that were produced without the noncompliance; and Dealers will also be instructed to check both the telltale and display at the first scheduled service (at 3,750 or 7,000 miles depending on variant) and will receive a technical service bulletin (TSB) with repair instructions for any vehicles in their inventory, which had not been inspected or repaired prior to shipment to dealers or for vehicles where the owner reports a telltale/multi-function display problem.

Discussion: NHTSA has reviewed and accepts Fuji's analyses that the noncompliance is inconsequential to motor vehicle safety. Fuji has provided documentation that the front passenger air bag suppression status telltale lamp does comply with all other safety performance requirements of the standard, except the illumination. NHTSA has reviewed all incoming complaints on the subject vehicles and found no complaints matching the subject noncompliance.

NHTSA's Response to Comments: NHTSA received a comment from Advocates for Highway & Auto Safety (Advocates) that recommended conditions under which to grant or deny concerning Fuji's petition.

Advocates expressed concern that the inability of the air bag telltale to accurately communicate the status of the front passenger air bag in the subject vehicles may mislead passengers to behave in a manner that is in conflict with the actual air bag status, thereby posing a significant danger to the passenger in the event of a crash. It provided the following examples as scenarios which, they claim, may place a passenger at risk.

1. ''The lack of a lighted indicator may be mistakenly interpreted to mean that the air bag itself has malfunctioned, or that only the air bag suppression feature is not working and that it is safe for an adult to use the front passenger seating position.''

2. ''[T]he lack of a lighted ''ON'' symbol on the telltale may be taken to mean that the air bag suppression is not activated and that it would be safe to place a rear facing infant restraint or a young child in the front passenger seat falsely assuming that the air bag would not deploy in the event of a crash.

Advocates believes that Subaru should be able to document the number of front passenger air bag telltales that were serviced, found to be malfunctioning, and were repaired out of the 3,405 affected Subaru Legacys and Outbacks that were shipped to dealers during the 10 month period before Subaru identified the problem since owners would have had ample time to notice a malfunction of the telltale and return their vehicle to the dealer for repair. Advocates recommended that if the repair data indicate that many or most of the noncompliant vehicles (27 of 3,405 potentially affected, as estimated by Subaru) have been repaired, that NHTSA should grant the petition, assuming that the agency agrees with Subaru's 0.8 percent noncompliance rate. Furthermore, it recommended that if the agency believes Subaru's 0.8 percent noncompliance rate is not reliable, or if many or most of the estimated 27 noncompliant vehicles have not been repaired, then the agency should deny the petition.

Advocates stated that ''NHTSA has on a number of occasions stated that noncompliance in even a single vehicle is significant, and therefore not inconsequential, if the failure to comply poses a threat to occupant safety'' and ''NHTSA has pointed out that small numbers or low percentages of noncompliant vehicles do not provide the basis for granting of a petition for inconsequential noncompliance.'' Though these assertions are correct, the agency has decided to grant Fuji's request for inconsequentiality for reasons other than the low number of vehicle that Subaru had calculated to be noncompliant. These reasons are as follows:

- Fuji issued a technical service bulletin (TSB) to its dealerships on July 16, 2009, that described the repair procedure for vehicles with inoperative passenger air bag status telltale lamps. This led to the repair of 28 vehicles

[1] The 2010 Subaru Legacy and Outback models' telltale has both an air bag suppression status indicator for ON and OFF. Thus, either ON or OFF on the telltale should be illuminated whenever the ignition is on.

which agrees with Fuji's initial estimate of 27 vehicles.

• As of April 10, 2013, a total of 144 consumer complaints have been received by NHTSA for the 2010 Subaru Legacy and Outback models. None of these complaints are related to the problem described by Subaru in their petition for inconsequentiality.

• As described in Fuji's petition, power is supplied to the passenger air bag status telltale lamp and the multifunction display with the same wiring harness connector. If the telltale does not receive power due to an open circuit from a loose connector, the entire multi-function display will also not illuminate and will be inoperable. Fuji believes this condition will be apparent to the consumer and would lead them to have the vehicle serviced. There were no consumer complaints reported to NHTSA related to this problem.

• Fuji explained that, based upon their supplier's vibration testing, the fault would not occur on a vehicle that originally had a functioning passenger air bag status telltale lamp and multifunction display. There were no consumer complaints reported to NHTSA related to loss of illumination of the telltale lamp and/or multifunction display.

Given the absence any related consumer complaints to date, the conspicuous nature of the problem on any vehicles with the fault, and Fuji's action to put in place a procedure to repair the few that did, the agency does not believe there is a significant risk to the motoring public in this specific case.

NHTSA Decision: In consideration of the foregoing, NHTSA has decided that Fuji met its burden of persuasion that the FMVSS No. 208 noncompliance with respect to the front passenger air bag suppression status telltale lamp described in Fuji's Noncompliance Information Report is inconsequential to motor vehicle safety. Accordingly, Fuji's petition is hereby granted and the Fuji is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the 3,405 noncompliant vehicles that Fuji no longer controlled at the time that it determined that a noncompliance existed in the subject vehicles.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Issued On: May 6, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–11089 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0142; Notice 2]

Pirelli Tire LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of Petition Grant.

SUMMARY: Pirelli Tire LLC (Pirelli), has determined that approximately 30,881 Pirelli Pzero Nero M+S and Scorpion Zero Asimmetrico replacement tires produced between September 2, 2007, and December 12, 2009, do not fully comply with the tire labeling requirements of paragraphs S5.5 and S7.3 of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* On March 12, 2010, Pirelli filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports.*

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, Pirelli has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Specifically, Pirelli submitted the original petition dated March 12, 2010, and a supplement to the original petition dated April 12, 2010.

Notice of receipt of Pirelli's petition was published, with a 30-day public comment period, on November 9, 2010, in the **Federal Register** (75 FR 68855). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2010–0142.''

Contact Infromation: For further information on this decision, contact Mr. Jack Chern, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–0661, facsimile (202) 366–7002.

Tires Involved: Affected are approximately 30,881 Pirelli Pzero Nero M+S and Scorpion Zero Asimmetrico replacement tires produced between September 2, 2007, and December 12, 2009,—in the tire sizes indicated in the following list—have the subject noncompliance:

P245/45ZR17 95W, Pzero Nero M+S
P235/45ZR17 94W, Pzero Nero M+S
P235/40ZR18 91W, Pzero Nero M+S
P215/35ZR18 84W, Pzero Nero M+S
P215/35ZR19 85W, Pzero Nero M+S
265/35ZR22 102W Extra Load, Scorpion Zero Asimmetrico
295/30ZR22 103W Extra Load, Scorpion Zero Asimmetrico
305/35ZR23 111W Extra Load, Scorpion Zero Asimmetrico
265/45ZR20 108W Extra Load, Scorpion Zero Asimmetrico

Summary of Pirelli's Analysis and Arguments: Pirelli described the noncompliance as the absence of either the complete or partial tire identification number (TIN) on the inner tire sidewall as required by paragraphs S5.5 and S7.3 of FMVSS No. 139.

Pirelli argues that because all of the affected tires have an asymmetric tread pattern that can only be correctly installed with the intended outer sidewall facing the outside of the vehicle. Pirelli also points out that asymmetric tires represent a very small percentage of the overall tire market.

Pirelli explained that all of the affected tires are stenciled on the intended outboard sidewall with the lettering OUTER in four different languages (English, French, German and Italian).

Pirelli further explained that the non-compliance was identified on February 26, 2010, during an inspection of mold branding at the plant that produced the subject tires. Pirelli then examined related production records in order to accurately identify the specific noncompliant tires. All molds are being modified or have been modified to ensure that the appropriate TIN information is contained on both sidewalls for future production.

Pirelli provided the following basis of why they believe the subject noncompliance is inconsequential to motor vehicle safety:

> While the subject tires are noncompliant with paragraph S5.5 of FMVSS No. 139 for labeling, the noncompliance has an inconsequential effect on tire performance and motor vehicle safety because all of the affected tires meet or exceed all of the

minimum performance requirements of FMVSS No. 139.

In addition, the Company mentioned the existence of certain factors that facilitates and encourages proper installation and thus provide accessibility and visibility of the full TIN on the outboard sidewall:

Pirelli's internal policy allows dealers to sell these asymmetric tires only in pairs or in groups of four. As a result, these replacement tires are installed either on both sides of the rear axle or on all four locations. The odds of even one tire being mounted incorrectly are extremely remote, and the odds of two or four tires being mounted the wrong way are even more remote.

All subject tires are either Pzero Nero M+S or Scorpion Zero Asimmetrico. Both product families are ultra high performance tires; their asymmetric tread design is one of the main features sought by consumers for the following reasons: precision handling in all conditions; full and compact external shoulder blocks for increased safety and dry handling performance; and inner shoulders designed to maximize traction with deeper and more regular cuts. These benefits are obtained only if the tires are mounted with the outer sidewall pointing to the outside of the vehicle. Having paid a substantial price to obtain these performance characteristics, the customers seek to ensure that their tires are installed correctly.

Pirelli's product literature and training procedures reinforce the message on proper mounting.

Pirelli provides extensive training to its authorized dealers, and that training focuses specifically on the need to mount asymmetric tires in the correct way.

A second TIN number (on the inboard side of the tire) is not necessary either to ensure traceability or to allow consumers to operate their vehicles safely.

Pirelli has not received a single complaint from any consumer, dealer, law enforcement agency, or other source that indicated any difficulty or problem in finding the full TIN, including the date code on its asymmetrical tires.

Pirelli collects and tracks data on warranty claims for all of tires, including the tires at issue here. The warranty data confirm that these tires have performed extremely well in the field. The number of claims is very small, and there have been no claims involving property damage.

In summation, for the reasons stated above, Pirelli believes that the described noncompliance concerning the tire labeling requirements of paragraphs S5.5 and S7.3 of FMVSS No. 139 are inconsequential and do not present a risk to motor vehicle safety. Thus, Pirelli requests that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120, should be granted. In a supplement to its petition Pirelli requested that if NHTSA decides to deny the petition, that at a minimum, NHTSA exempt the company from the remedy requirements of 49 U.S.C. 30120. Rather than replacing all tires subject to any such recall, Pirelli suggests that it would instead issue recall notices to all end users who can be located. Pirelli then would have its dealers inspect the tires. If the tires are properly mounted, with the TINs facing the outboard side of the vehicle, the tires would be left on the vehicle. Finally, if any tires were found to be mounted with the outboard sidewalls facing inward (which is extremely unlikely), the tires would be remounted in the appropriate way.

Requirement Background

Paragraph s5.5 of FMVSS No. 139 requires in pertinent part:

S5.5 *Tire Markings.* Except as specified in paragraphs (a) through (i) of S5.5, each tire must be marked on each sidewall with the information specified in S5.5(a) through (d) and on one sidewall with the information specified in S5.5(e) through (i) according to the phase-in schedule specified in S7 of this standard. The markings must be placed between the maximum section width and the bead on at least one sidewall, unless the maximum section width of the tire is located in an area that is not more than one-fourth of the distance from the bead to the shoulder of the tire. If the maximum section width falls within that area, those markings must appear between the bead and a point one-half the distance from the bead to the shoulder of the tire, on at least one sidewall. The markings must be in letters and numerals not less than 0.078 inches high and raised above or sunk below the tire surface not less than 0.015 inches.

S5.5.1 Tire identification number.

(a) Tires manufactured before September 1, 2009. Each tire must be labeled with the tire identification number required by 49 CFR part 574 on a sidewall of the tire. Except for retreaded tires, either the tire identification number or a partial tire identification number, containing all characters in the tire identification number, except for the date code and, at the discretion of the manufacturer, any optional code, must be labeled on the other sidewall of the tire.

(b) Tires manufactured on or after September 1, 2009. Each tire must be labeled with the tire identification number required by 49 CFR part 574 on the intended outboard sidewall of the tire. Except for retreaded tires, either the tire identification number or a partial tire identification number, containing all characters in the tire identification number, except for the date code and, at the discretion of the manufacturer, any optional code, must be labeled on the other sidewall of the tire. Except for retreaded tires, if a tire does not have an intended outboard sidewall, the tire must be labeled with the tire identification number required by 49 CFR part 574 on one sidewall and with either the tire identification number or a partial tire identification number, containing all characters in the tire identification number except for the date code and, at the discretion of the manufacturer, any optional code, on the other sidewall * * *

NHTSA's Analysis of Perelli's Reasoning: NHTSA does agree with Pirelli's assessment that the noncompliance with FMVSS No. 139 is inconsequential to motor vehicle safety. As discussed below, the tire markings required by paragraph S5.5 of FMVSS No. 139 provide valuable information to assist consumers in determining if their tires are the subject of a safety recall. However, in these asymmetric tires, the TIN will always be on the intended outboard sidewall.

Paragraph S5.5.1(b) of FMVSS No. 139 requires that radial tires manufactured on or after September 1, 2009 for motor vehicles less than 10,000 GVWR be permanently labeled with: (1) a full TIN required by 49 CFR Part 574 on the intended outboard sidewall of the tire; (2) except for retreaded tires, either the full or a partial TIN containing all characters in the TIN, except for the date code, and at the discretion of the manufacturer, any optional code, must be labeled on the other sidewall of the tire.[1]

Tire recalls in the year 2000 highlighted the difficulty that consumers experienced when attempting to determine whether a tire is subject to a recall when a tire is mounted so that the sidewall bearing the TIN faces inward i.e., underneath the vehicle. After a series of congressional hearings about the safety of and experiences regarding the tires involved in those recalls, Congress passed and the President signed into law the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act on November 1, 2000. Pub. L. 106–414. 114 Stat. 1800.

One of the matters addressed by the TREAD Act was tire labeling. Section 11 of the TREAD Act required a rulemaking to improve the labeling of tires to assist consumers in identifying tires that may be the subject of a recall.

In response to the TREAD Act's mandate, NHTSA published a final rule that, among other things, required that the TIN be placed on a sidewall of the tire and a full or partial TIN be placed on the other sidewall. See 67 FR 69600, 69628 (November 18, 2002), as amended

[1] Tires manufactured after September 1, 2009 must be labeled with the TIN on the intended outboard sidewall of a tire and either the TIN or partial TIN on the other sidewall. 49 CFR 571.139 S5.5.1(b). If a tire manufactured after September 1, 2009 does not have an intended outboard sidewall, one sidewall must be labeled with the TIN and the other sidewall must have either a TIN or partial TIN. Id.

69 FR 31306 (June 3, 2004). In the preamble to the 2002 final rule, the agency identified the safety problem which prompted the issuance of the rule. 67 FR at 69602, 69606, and 69610. The agency explained that when tires are mounted so that the TIN appears on the inward facing sidewalls, motorists have three difficult and inconvenient options for locating and recording the TINs. Consumers must either: (1) Slide under the vehicle with a flashlight, pencil and paper and search the inside sidewalls for the TINs; (2) remove each tire, find and record the TIN, and then replace the tire; or (3) enlist the aid of a garage or service station that can perform option 1 or place the vehicle on a vehicle lift so that the TINs can be found and recorded. Without any TIN information on the outboard sidewalls of tires, the difficulty and inconvenience of obtaining the TIN by consumers results in a reduction of the number of people who respond to a tire recall campaign and the number of motorists who unknowingly continue to drive vehicles with potentially unsafe tires.

Pirelli suggests that this noncompliance does not preclude motorists from checking the inboard sidewall if the TIN is not found on the outboard sidewall. However, since asymmetric tires are specially constructed for certain performance parameters, and the TIN is marked on the intended outboard sidewall, the Agency agrees that it is extremely unlikely that the tires will be mismounted with the inboard sidewall facing outboard.

However, even though FMVSS No. 139 now requires TIN markings on both sidewalls of a tire so that consumers can readily determine if a tire is subject to a safety recall, in this case it is extremely unlikely that one or more of the asymmetric tires will be incorrectly mounted with the intended outboard sidewall facing inboard.

NHTSA Decision: In consideration of the foregoing, NHTSA has decided that the petitioner has met its burden of persuasion that the noncompliance described is inconsequential to motor vehicle safety. Accordingly, Pirelli's petition is hereby granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, these provisions only apply to the 30,881[2] vehicles that Pirelli no longer controlled at the time it determined that the noncompliance existed.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.95 and 501.8)

Issued on: May 1, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–11091 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–59–P

[2] Pirelli's petition, which was filed under 49 CFR part 556, requests an agency decision to exempt Pirelli as a Tire manufacturer from the notification and recall responsibilities of 49 CFR part 573 for the 30,881 affected tires. However, a decision on this petition cannot relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Pirelli notified them that the subject noncompliance existed.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2008–0210; Notice 2]

Newell Coach Corporation, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of petition.

SUMMARY: Newell Coach Corporation (Newell) has determined that certain motor homes that it manufactured between June 17, 1996 and August 26, 2008, do not fully comply with paragraph S5.3 of Federal Motor Vehicle Safety Standard (FMVSS) No. 120 *Tire Selection and Rims for Motor Vehicles with a GVWR of More than 4,536 Kilograms (10,000 pounds).* Newell filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports* on September 9, 2008.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR Part 556, Newell has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of the petition was published, with a 30-day public comment period, on December 19, 2008 in the **Federal Register** (73 FR 77876). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2008–0210.''

Contact Information: For further information on this decision, contact Mr. John Finneran, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–0654, facsimile (202) 366–5930.

Tires Involved: Affected are approximately 456 motor homes manufactured by Newell between June 17, 1996 and August 26, 2008. Newell explains that the noncompliance is that the tire and rim information lettering engraved on the vehicles' certification labels[1] is only 1.8 millimeters high, as opposed to the 2.4 millimeter height required under paragraph S5.3 of FMVSS No. 120.

Summary of Newell's Petition: Newell stated that it discovered the noncompliance after investigating an inquiry from National Highway Traffic Safety Administration (NHTSA) concerning readability of the tire and rim information on the vehicles' certification labels.

Newell argues that while the required tire and rim information lettering is only 0.6 mm (about 1/45 of an inch) shorter than the 2.4 mm height required by the standard that it creates no risk to motor vehicle safety. Newell believes that all of the relevant information is set forth on the certification label, and that it is easily readable.

Newell further states that for vehicles manufactured from 2002 through 2008, if an operator has difficulty reading the information on the certification label, the tire inflation information is available in the owner's manuals provided with the vehicles.

Newell additionally stated that it has provided tire inflation information in the Newell's News, a newsletter that Newell sends to its customers. Newell also points out that the rim size and type are marked on the wheels of the vehicle, and the tire designation is marked on the tires themselves, thus providing a further source for most of the information required by the standard.

Newell also believes that NHTSA has previously granted at least one petition for inconsequential noncompliance where the facts were almost identical to those stated in this petition. Moreover, Newell believes that on numerous occasions NHTSA has granted petitions

[1] 49 CFR Part 567 states the requirements for the certification label. FMVSS No. 120 states the requirements for tire and rim information included on a certification label.

for inconsequential noncompliance where there has been a complete omission of required tire and/or rim information on the certification label.

Finally, Newell notes that these vehicles have been on the road for up to 12 years, and the company has not received any consumer complaints regarding an inability to read the tire and rim information on the certification label.

Newell also stated that it has corrected the problem that caused these errors so that they will not be repeated in future production.

In summation, Newell states that it believes that because the noncompliances are inconsequential to motor vehicle safety that no corrective action is warranted.

NHTSA's Analysis and Decision: Section 5.3 of FMVSS 120 specifically states:

S5.3 Each vehicle shall show the information specified in S5.3.1 and S5.3.2 and, in the case of a vehicle equipped with a non-pneumatic spare tire, the information specified in S5.3.3, in the English language, lettered in block capitals and numerals not less than 2.4 millimeters high and in the format set forth following this paragraph. This information shall appear either—(a) and (b) . . .

NHTSA notes that the certification labels in question are constructed of clear polymer plates that are 3 mm in thickness. Lettering is engraved on the reverse side of the label plate. While the size of the lettering as measured on the back side of the label is only 1.8 mm in height, its apparent height when viewed from the front (intended viewing side) of the label is 2 mm.

The agency agrees with Newell that the certification labels on the subject vehicles are likely to achieve the safety purpose of the tire and rim labeling. First, the tire size, and cold inflation pressure information required by FMVSS No. 120 is correct and contained in the label, and maximum inflation pressure is marked on the tires and the rim size is marked on the rims. Second, based on NHTSA's inspection of the sample nonconforming label provided by Newell, the letters can be easily read. Third, while NHTSA does not agree with Newell's assertion that the owner's manuals and newsletters provide all the information described by Newell, the information provided does supplement the information provided on the subject label. Lastly, NHTSA has elected to not address Newell's assertions on previous petitions for inconsequential noncompliance.

In consideration of the foregoing, NHTSA has determined that Newell has met its burden of persuasion that the subject FMVSS No. 120 labeling noncompliance is inconsequential to motor vehicle safety. Accordingly, Newell's petition is hereby granted, and Newell is exempted from the obligation of providing notification of, and a remedy for, the subject noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to approximately 456 vehicles that Newell no longer controlled at the time that it determined that a noncompliance existed in the subject vehicles. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Newell notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at CFR 1.95 and 501.8.

Issued on: May 1, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–11093 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Research and Innovative Technology Administration

[Docket Number RITA–2008–0002]

Notice of Request for Approval To Continue To Collect New Information: Confidential Close Call Reporting System

AGENCY: Bureau of Transportation Statistics (BTS), Research and Innovative Technology Administration (RITA), U.S. Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, this notice announces that the Bureau of Transportation Statistics (BTS) intends to request the Office of Management and Budget (OMB) renew the information collection request for the Close Calls project. This data collection effort is in support of a five-year research study aiming at improving rail safety by analyzing information on close calls and other unsafe occurrences in the rail industry. The ongoing research study is conducted by the Office of Human Factors in the Federal Railroad Administration and is designed to identify safety issues and propose corrective actions based on voluntary reports of close calls submitted to BTS. This collection is necessary because data on close calls are not normally reported to the railroad carriers or the Federal Railroad Administration. Continuous data collection for this research project is necessary to develop trends about rail safety and to improve railroad safety on an ongoing basis.

DATES: Comments must be received by July 9, 2013.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments by only one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically. Docket Number: RITA–2008–2002.
- *Mail:* Docket Management Facility (DMF), U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to mail address above between 9 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Identify all transmission with ''Docket Number RITA–2008–0002'' at the beginning of each page of the document.

Instructions: All comments must include the agency name and docket number for this notice. Paper comments should be submitted in duplicate. The DMF is open for examination and copying, at the above address from 9 a.m. to 5 p.m. EST, Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on Docket RITA–2008–0002.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that all comments received, including any personal information, will be posted and will be available on the Internet users, without change, at *www.regulations.gov*. You may review

DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; pages 19477–78) or you may review the Privacy Act Statement at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Demetra V. Collia, Bureau of Transportation Statistics, Research and Innovative Technology Administration, U.S. Department of Transportation, Office of Advanced Studies, RTS–31, E324–302, 1200 New Jersey Avenue SE., Washington, DC 20590–0001; Phone No. (202) 366–1610; Fax No. (202) 366–3383; email: *demetra.collia@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m., EST, Monday through Friday, except Federal holidays.

Data Confidentiality Provisions: The confidentiality of Close Calls data is protected under the BTS confidentiality statute (49 U.S.C. 111(k)) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002 (Public Law 107–347, Title V). In accordance with these confidentiality statutes, only statistical and non-identifying data will be made publicly available through reports. Further, BTS will not release to FRA or any other public or private entity any information that might reveal the identity of individuals or organizations mentioned in close call reports.

SUPPLEMENTARY INFORMATION:

I. The Data Collection

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; as amended) and 5 CFR Part 1320 require each Federal agency to obtain OMB approval to continue an information collection activity. BTS is seeking OMB approval for the following BTS information collection activity:

Title: Confidential Close Call Reporting System.

OMB Control Number: 2139–0010.

Type of Review: Approval to continue to collect new information: Confidential Close Call Reporting System (C^3RS).

Respondents: Employees of selected (pilot) railroad sites.

Number of Respondents: 3,100 (per annum).

Estimated Time per Response: 0.50 hours.

Frequency: Intermittent for approximately two (2) years. (Reports are submitted when there is a qualifying event, *i.e.* a close call occurs within a pilot site. The frequency of such an event is estimated to be two per day.)

Total Annual Burden: 365.00 hours.

II. Background

Collecting data on the nation's transportation system is an important component of BTS' mission and responsibility to the transportation community as stated in its authorizing statute (49 U.S.C. 6302). BTS and FRA share a common interest in promoting rail safety based on better data. To that end, FRA's Office of Safety is sponsoring the Confidential Close Call Reporting System (C^3RS) Demonstration Project to investigate the effectiveness of such a data collection system in improving rail safety. The data collection phase of this study was initiated in February, 2007 and is scheduled to continue for approximately 2 more years.

A close call represents a situation in which an ongoing sequence of events was stopped from developing further, preventing the occurrence of potentially serious safety-related consequences. This might include the following: (1) Events that happen frequently, but have low safety consequences; (2) events that happen infrequently but have the potential for high consequences (e.g., a train in dark territory proceeds beyond its authority); (3) events that are below the FRA reporting threshold (e.g., an event that causes a minor injury); and (4) events that are reportable to FRA but have the potential for a far greater accident than the one reported (e.g., a slow speed collision with minor damage to the equipment and no injuries.)

Employees involved in reporting a close call incident will be asked to fill out a report and participate in a brief, confidential interview. Employees will have the option to mail or submit the report electronically to BTS. Participants will be asked to provide information such as: (1) Name and contact information; (2) time and location of the event; (3) a short description of the event; (4) contributing factors to the close call; and (5) any other information that might be useful in determining a root cause of such event.

BTS collects close call reports submitted by railroad employees and protects the confidentiality of these data through its own statute (49 U.S.C. 6302(i)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA). In addition, BTS is developing an analytical database containing the reported data and other pertinent information to determine root causes of frequently reported close calls. The database is a valuable tool to railroad carriers and the FRA in their effort to identify safety issues and provide corrective measures before an accident occurs.

Voluntary reporting of close calls to a confidential system can provide a tool to identify and correct weaknesses in railroad safety systems before an accident actually occurs. The C^3RS demonstration project offers a voluntary, cooperative, non-punitive environment to communicate safety concerns. Through the analysis of close calls the FRA and the railroad community receive information about factors that may contribute to unsafe events and the error recovery mechanisms that prevented an adverse consequence from occurring. Such information is used to develop new training programs, identify root causes of potentially adverse events, assess risk and allocate resources to address those risks more efficiently. In addition, the database provides rail safety researchers with valuable information regarding precursors to safety risks and contributes to research and development of intervention programs aimed at preventing accidents and fatalities.

III. Request for Comments

BTS requests comments on any aspects of these information collections, including: (1) The accuracy of the estimated burden of 365 hours detailed in Section I; (2) ways to enhance the quality, usefulness, and clarity of the collected information; and (3) ways to minimize the collection burden without reducing the quality of the information collected, including additional use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on May 3, 2013.

Patricia Hu,

Director, Bureau of Transportation Statistics, Research and Innovative Technology Administration.

[FR Doc. 2013–11190 Filed 5–9–13; 8:45 am]

BILLING CODE 4910–HY–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Submission for OMB Review: Disclosure of Financial and Other Information by National Banks

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information

collection, as required by the Paperwork Reduction Act of 1995.

Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, ''Disclosure of Financial and Other Information by National Banks.'' The OCC also gives notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before June 10, 2013.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0182, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *regs.comments@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0182, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: You may request additional information or a copy of the collection from Johnny Vilela or Mary H. Gottlieb, OCC Clearance Officers, (202) 649–5490, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, the OCC has submitted the following proposed collection of information to OMB for review and clearance.

Title: Disclosure of Financial and Other Information by National Banks (12 CFR 18).

OMB Control No.: 1557–0182.

Type of Review: Extension, without revision, of a currently approved collection.

Description: The collections of information are found in 12 CFR 18.3, 18.4, and 18.8. Section 18.3 requires the preparation of an annual disclosure statement and specifies how it must be made available to shareholders. Section 18.4 outlines what information the disclosure statement must contain, and provides that a bank may supplement its annual disclosure statement with an optional narrative. Lastly, § 18.8 requires that a national bank promptly furnish its annual disclosure statement upon request.

This program of periodic financial disclosure is needed not only to facilitate informed decision making by existing and potential customers and investors, but also to improve public understanding of, and confidence in, the financial condition of individual national banks and the national banking system. Further, financial disclosure reduces the likelihood that the market will overreact to incomplete information.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 1,338.

Estimated Number of Responses: 1,338.

Estimated Annual Burden: 669 hours.

Frequency of Response: On occasion.

Comments: The OCC published a 60-day **Federal Register** notice on February 17, 2013. (78 FR 13400). No comments were received.

Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 3, 2013.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2013–11122 Filed 5–9–13; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Amendment to System of Records.

SUMMARY: As required by the Privacy Act of 1974, 5 U.S.C. 552a(e), notice is hereby given that the Department of Veteran Affairs (VA) is amending the system of records currently entitled ''Health Professional Scholarship Program—VA'' (73VA14) as set forth in the **Federal Register** 74 FR 62390. VA is amending the system of records by revising the System Name, System Location, Categories of Individuals Covered by the System, Categories of Records in the System, Authority for Maintenance, Purpose, Storage, Retrievability, Safeguards, System Manager(s) and Address, Notification Procedure, Record Access Procedure, and Records Source Category. VA is republishing the system notice in its entirety.

ADDRESSES: Written comments concerning the proposed new system of records may be submitted through *www.regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online

through the Federal Docket Management System (FDMS) at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration (VHA) Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; telephone (704) 245–2492.

SUPPLEMENTARY INFORMATION: VA is renaming the system of records from Health Professional Scholarship Program—VA to Health Professional Scholarship Program, and Visual Impairment and Orientation and Mobility Professional Scholarship Program—VA. The system number is changed from 73VA14 to 73VA10A2A to reflect the current organizational alignment.

The section titled ''The Location'' has been amended to remove that records will be maintained at the Office of Academic Affiliations (OAA), Veterans Health Administration, Veterans Administration Central Office (VACO), 810 Vermont Avenue NW., Washington, DC 20420, and the Data Processing Center, Department of Veterans Affairs, 1615 East Woodward Street, Austin, TX 78772 to include that records will be maintained at the Healthcare Talent Management (HTM), Scholarships and Nursing Education Office, Veterans Health Administration, Department of Veterans Affairs, 1250 Poydras Street, Suite #1000, New Orleans, LA, 70113.

The section titled ''The Category of Individuals Covered by the System'' has been amended to include individuals who apply for and are awarded scholarships under the provisions of VA's Visual Impairment and Orientation and Mobility Professional Scholarship Program (VIOMPSP).

The section titled ''The Category of Records in the System'' is amended to reflect mailing and email addresses, employing facility number (if applicable), home and work telephone numbers, Social Security number, an alternative person of contact, job title, current education level, degree sought, description of the academic program covered by the scholarship, name and address of the academic institution, the starting and completion dates of the employee's academic program, and awards and activities. Records may include memoranda submitted by the employees, calculations for service obligations, copies of letters and memoranda from employees making the requests and in correspondence to employees and appropriate local program officials delineating the decisions on such requests. Account number and routing number, the obligated service incurred, and the location, start, and end dates of the service obligation period are also included.

The Authority for Maintenance is being changed from Title 38, U.S.C. 210(c), 4141–4146 and 4118 to Title 38, U.S.C. 7611–7619, 7635–7636.

The section titled ''The Purpose'' in this system of records is being amended to reflect Public Law 111–163, signed on May 5, 2010, which was reauthorized by the Health Professional Scholarship Program (HPSP) through December 31, 2014, and established the VIOMPSP. The records and information may be used for determining and documenting individual applicant eligibility for scholarship awards, selecting applicants to receive awards, calculating the service commitments for program participants, ensuring program financial accountability, monitoring educational progress of participants, monitoring the employment status of scholarship participants during their periods of obligated service, terminating the employee from the program (upon completion or breach), and evaluating and reporting program results and effectiveness. The information would also be used to determine the financial liability of participants who breach their HPSP or VIOMPSP agreement.

The section titled ''Storage'' is being amended to state that records are maintained on paper, electronic media, and computer printouts by HTM. Records stored on electronic media are maintained on a VA-approved and managed, password protected, secure local area network (LAN) located within HTM office spaces.

The section titled ''Retrievability'' is being amended to include an equivalent participant account number assigned by HTM. Safeguards is being amended to include records stored on electronic media and maintained on a VA-approved and managed, password protected, secure LAN located within HTM office spaces.

The sections titled ''System Manager(s) and Address'', ''Notification Procedure'', and ''Record Access Procedure'' have been amended to state: Director, HTM (10A2A8), Veterans Health Administration, Department of Veterans Affairs, 1250 Poydras Street, Suite #1000, New Orleans, Louisiana 70113.

The section titled ''Records Source Category'' has been amended to remove the VA Data Processing Center (DPC).

Approved: April 22, 2013.

Jose D. Riojas,

Interim Chief of Staff, Department of Veterans Affairs.

73VA10A2A

SYSTEM NAME:

Health Professional Scholarship Program, and Visual Impairment and Orientation and Mobility Professional Scholarship Program—VA.

SYSTEM LOCATION:

Active records will be maintained at HTM, Scholarships and Nursing Education Office, Veterans Health Administration, Department of Veterans Affairs, 1250 Poydras Street, Suite #1000, New Orleans, LA, 70113. Complete records will be maintained only at this address.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who apply for and are awarded scholarships under the provisions of the Veterans Health Administration Health Professional Scholarship Program (HPSP) in a field leading to an appointment under paragraph (1) or (3) of section 7401 of Title 38, and individuals who apply for and are awarded scholarships under the provisions of the Veterans Health Administration Visual Impairment and Orientation and Mobility Professional Scholarship Program (VIOMPSP) in a program of study leading to an appointment as a qualified blind rehabilitation specialist.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records (or information contained in records) in this system may include: personal identification information related to the application material, to award processes, to employment, to obligated service, and to requests for waivers or suspensions of obligated service or financial indebtedness to VA. The application for an HPSP or VIOMPSP award includes the applicant's full name, mailing and email addresses, employing facility number (if applicable), home and work telephone numbers, Social Security number, an alternative person of contact, job title, current education level, degree sought, description of the academic program covered by the scholarship, name and address of the academic institution, the starting and completion dates of the employee's academic program, awards and activities. Records may include memoranda submitted by the employees, calculations for the service obligations, copies of letters and memoranda from employees making the requests and in correspondence to

employees and appropriate local program officials delineating the decisions on such requests. Records for applicants selected will also include the award amount, the name of the participant's financial institution, account number and routing number, the obligated service incurred, and the location, start, and end dates of the service obligation period.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

38 U.S.C. §§ 7611–7619, 7635–7636.

PURPOSE(S):

These records support the HPSP and VIOMPSP. The HPSP was established by Public Law 96–330, and awarded scholarships to 3,330 students between 1982 through 1995 earning baccalaureate and master's degrees in nursing and other health professions. Public Law 111–163, signed on May 5, 2010, reauthorized the HPSP through December 31, 2014, and established the VIOMPSP. The records and information may be used for determining and documenting individual applicant eligibility for scholarship awards, selecting applicants to receive awards, calculating the service commitments for program participants, ensuring program financial accountability, monitoring educational progress of participants, monitoring the employment status of scholarship participants during their periods of obligated service, terminating the employee from the program (upon completion or breach), and evaluating and reporting program results and effectiveness. The information would also be used to determine the financial liability of participants who breach their HPSP or VIOMPSP agreement.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 45 CFR Parts 160 and 164, *i.e.,* individually identifiable health information, and 38 U.S.C. 7332, *i.e.,* medical treatment information related to drug abuse, alcoholism or alcohol abuse, sickle cell anemia or infection with the human immunodeficiency virus, that information cannot be disclosed under a routine use unless there is also specific statutory authority in 38 U.S.C. 7332 and regulatory authority in 45 CFR Parts 160 and 164 permitting disclosure.

1. The record of an individual who is covered by this system may be disclosed to a member of Congress or staff person acting for the member when the member or staff person requests the record on behalf of and at the request of that individual.

2. Any information in this system may be disclosed to a Federal, state, or local agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision on: the hiring, transfer or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit by that agency.

3. Any information in this system may be disclosed to a Federal, state, or local agency maintaining civil or criminal violation records, or other pertinent information such as prior employment history, prior Federal employment background investigations, and personal or educational background in order for VA to obtain information relevant to the hiring, transfer or retention of an employee, the letting of a contract, the granting of a security clearance, or the issuance of a grant or other benefit.

4. Any information in this system may be disclosed to a Federal agency in order to determine if an applicant has an obligation for service under another Federal program, thus rendering the applicant ineligible for a VA scholarship (38 U.S.C. 4142(a)(4)).

5. Any information in this system pertaining to individuals eligible for scholarships may be disclosed to educational institutions in order to assist in the administration of this program.

6. Award payment information may be disclosed to the Department of Treasury to permit delivery of scholarship-related checks to students and to educational institutions.

7. Any information in this system, including available identifying information regarding the debtor, such as name, place of birth, and date of birth of the debtor may be disclosed under this routine use to Federal, state, or consumer reporting agencies in order to obtain current name, address, locator, and credit report in connection with any proceeding for the collection of an amount owed to the United States by virtue of an individual's participation in the VA Health Professional Scholarship Program and Visual Impairment and Orientation and Mobility Professional Scholarship Program.

8. Any information in this system may be disclosed to the Department of Justice (DOJ), including U.S. Attorneys, in order for VA to respond to pleadings, interrogatories, orders or inquiries from DOJ, and to supply DOJ with information in any phase of litigation or in any case or controversy involving VA.

9. Any information in this system may be disclosed to educational institutions, previous employers or individuals providing references to verify the authenticity of the application.

10. Records from this system of records may be disclosed to a Federal Agency or to a state or local government licensing board and to the Federation of State Medical Boards or a similar non-government entity which maintains records concerning individuals' employment histories or concerning the issuance, retention, or revocation of licenses, certifications, or registration necessary to practice an occupation, profession, or specialty, in order for the Agency to obtain information relevant to an Agency decision concerning the hiring, retention, or termination of an employee or to inform a Federal Agency, licensing boards, or the appropriate nongovernment entities about the health care practices of a terminated, resigned, or retired health care employee whose professional health care activity so significantly failed to conform to generally accepted standards of professional medical practice as to raise reasonable concern for the health and safety of patients in the private sector or from another Federal agency. These records may also be disclosed as part of an ongoing computer matching program to accomplish these purposes.

11. Identifying information in this system, including name, address, Social Security number, and other information as is reasonably necessary to identify such individual, may be disclosed to the National Practitioner Data Bank at the time of hiring or clinical privileging/reprivileging of health care practitioners, and other times as deemed necessary by VA, in order for VA to obtain information relevant to a Department decision concerning the hiring privileging/reprivileging, retention, or termination of the applicant or employee.

12. Relevant information from this system of records may be disclosed to the National Practitioner Data Bank or State Licensing Board in the state(s) in which a practitioner is licensed, in which the VA facility is located, or in which an act or omission occurred upon which a medical malpractice claim was based when VA reports information concerning: (1) Any payment for the benefit of a physician, dentist, or other licensed health care practitioner which was made as the result of a settlement or judgment of a claim of medical malpractice if an appropriate determination is made in accordance with agency policy that payment was related to substandard care, professional incompetence, or professional misconduct on the part of the individual; (2) a final decision which

relates to possible incompetence or improper professional conduct that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days; or (3) the acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist either while under investigation by the health care entity relating to possible incompetence or improper professional conduct, or in return for not conducting such an investigation or proceeding. These records may also be disclosed as part of a computer matching program to accomplish these purposes.

13. Disclosure may be made to the National Archives and Records Administration (NARA) and the General Services Administration (GSA) in records management inspections conducted under authority of Title 44 U.S.C.

14. Disclosure of relevant information may be made to individuals, organizations, private or public agencies, or other entities with whom VA has a contract or agreement, or where there is a subcontract to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

15. VA may disclose on its own initiative any information in the system, except the names and home addresses of Veterans and their dependents, that is relevant to a suspected or reasonably imminent violation of the law whether civil, criminal, or regulatory in nature and whether arising by general or program statute or by regulation, rule, or order issued pursuant thereto, to a Federal, state, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule, or order. VA may also disclose on its own initiative the names and addresses of Veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal, or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, or order issued pursuant thereto.

16. Disclosure to other Federal agencies may be made to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

17. VA may, on its own initiative, disclose any information or records to appropriate agencies, entities, and persons when: (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by the Department to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724, as the terms are defined in 38 U.S.C. 5727.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM STORAGE:

Records are maintained on paper, electronic media, and computer printouts by HTM. Records stored on electronic media are maintained on a VA-approved and managed, password protected, secure local area network (LAN) located within HTM office spaces and safeguarded as described above.

RETRIEVABILITY:

Records are retrievable by use of the award number, or an equivalent participant account number assigned by HTM, Social Security number, and the name of the individual.

SAFEGUARDS:

Access to the basic file in HTM is restricted to authorized VA employees and vendors. Access to the office spaces where electronic media is maintained within HTM is further restricted to specifically authorized employees and is protected by contracted building security services. Records (typically computer printouts) at HTM will be kept in locked files and made available only to authorized personnel on a need to-know basis. During non-working hours the file is locked and the building is protected by contracted building security services. Records stored on electronic media are maintained on a VA-approved and managed, password protected, secure LAN located within HTM office spaces and safeguarded as described above.

RETENTION AND DISPOSAL:

Records will be maintained and disposed of in accordance with records disposition authority approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Healthcare Talent Management (10A2A8), Veterans Health Administration, Department of Veterans Affairs, 1250 Poydras Street, Suite #1000, New Orleans, Louisiana 70113.

NOTIFICATION PROCEDURE:

Any individual who wishes to determine whether a record is being maintained in this system under his or her name or other personal identifier, or wants to determine the contents of such records, should submit a written request or apply in person to the Director, Healthcare Talent Management (10A2A8), Veterans Health Administration, Department of Veterans Affairs, 1250 Poydras Street, Suite #1000, New Orleans, Louisiana 70113.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of VA records in this system may write, call, or visit the Director, Healthcare Talent Management (10A2A8), Veterans Health Administration, Department of Veterans Affairs, 1250 Poydras Street, Suite #1000, New Orleans, Louisiana 70113. The telephone number is (504) 565–4900.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information contained in the records is obtained from the individual, references given in application material, educational institutions, VA medical facilities, other Federal agencies, state agencies, and consumer reporting agencies.

[FR Doc. 2013–11158 Filed 5–9–13; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 418, 482, et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 482, 485, and 489

[CMS–1599–P]

RIN 0938–AR53

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems. Some of the proposed 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) and other legislation. These proposed changes would be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in this proposed rule. We also are proposing to update the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The proposed updated rate-of-increase limits would be effective for cost reporting periods beginning on or after October 1, 2013.

We are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implement certain statutory changes made by the Affordable Care Act. Generally, these proposed changes would be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in this proposed rule.

In addition, we are proposing a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. We are proposing to establish new requirements or revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare.

We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program. In addition, we are proposing to revise the conditions of participation (CoPs) for hospitals relating to the administration of vaccines by nursing staff as well as the CoPs for critical access hospitals relating to the provision of acute care inpatient services.

DATES: *Comment Period:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EDT on June 25, 2013.

Application Deadline for GME FTE Resident Slots from Closed Hospital. Applications from hospitals to receive GME FTE resident slots from a hospital's closure as described in section V.J.3.c. of the preamble of this proposed rule must be received, not postmarked, by 5 p.m. EST on July 25, 2013.

ADDRESSES: When commenting, please refer to file code CMS–1599–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code CMS–1599–P to submit comments on this proposed rule.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1599–P, P.O. Box 8011, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1599–P, 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 (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the HHH 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. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call 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, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Tzvi Hefter, (410) 786–4487, and Ing-Jye Cheng, (410) 786–4548, Operating Prospective Payment, MS–DRGs, Hospital Acquired Conditions (HAC), 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), and Postacute Care Transfer Issues.

Michele Hudson, (410) 786–4487, and Judith Richter, (410) 786–2590, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Mollie Knight, (410) 786–7948 and Bridget Dickensheets, (410) 786–8670, Market Basket for IPPS Hospitals and LTCHs Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and

Readmission Measures for Hospitals 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.

Allison Lee, (410) 786–8691 and Jeffrey Buck, (410) 786–0407, Inpatient Psychiatric Facility Quality Reporting Issues.

Sarah Fahrendorf, (410) 786–3112, Conditions of Participation (CoPs) for CAHs Issues.

Commander Scott Cooper, USPHS, (410) 786–9465, Hospital Conditions of Participation (CoPs)—Pneumococcal Vaccine Issues.

Jennifer Dupee, (410) 786–6537, and Jennifer Phillips, (410) 786–1023, Medical Review Criteria for Hospital Inpatient Services under Medicare Part A.

Ann Marshall, (410) 786–3059, Requirement for Physician Order for Payment of Hospital Inpatient Services under Medicare Part A.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following 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.

Comments received timely also will be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1 (800) 743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government 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 this 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 will be available only through the Internet. The IPPS tables for this proposed rule are available only 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 2014 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2014 proposed 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–1599–P. For complete details on the availability of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS 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
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
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
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
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*
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
CoP [Hospital] condition of participation
CPI Consumer price index
CRNA Certified registered nurse anesthetist
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
ECI Employment cost index
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
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
GAAP Generally Accepted Accounting Principles
GAF Geographic Adjustment Factor
GME Graduate medical education

HAC Hospital-acquired condition
HAI Healthcare-associated infection
HBIPS Hospital-based inpatient psychiatric services
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
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
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
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
IVR Interactive voice response
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
LTCHQR Long-Term Care Hospital Quality Reporting
MA Medicare Advantage
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MCV Major cardiovascular condition
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
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
NOP Notice of Participation
NQF National Quality Forum
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991 (Pub. L. 104–113)
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
OPM U.S. Office of Personnel Management
OQR [Hospital] Outpatient Quality Reporting
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
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
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
QIG Quality Improvement Group, CMS
QIO Quality Improvement Organization
RCE Reasonable compensation equivalent
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
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCIP Surgical Care Improvement Project
SFY State fiscal year
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
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
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
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2014 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; and cancer hospitals. 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 specifies 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)(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.

• 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 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 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.

• 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, effective for discharges beginning on October 1, 2014.

• 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 3313 of the Affordable Care Act, which provides for a reduction to disproportionate share 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 now requires that, for ''fiscal year 2014 and each subsequent fiscal year,'' ''subsection (d) hospitals'' that would otherwise receive a ''disproportionate share payment . . . made under subsection (d)(5)(F)'' will receive two separate payments: (1) 25 percent of the amount they previously would have received under subsection (d)(5)(F) 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 subsection (d)(5)(F); (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(s)(4) of the Act, as added and amended by section 3401(f) and 10322(a) of the Affordable Care Act, respectively, which requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Under this program, known as the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, beginning with FY 2014, the Secretary must reduce any annual update to a standard Federal rate for discharges occurring during a fiscal year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable fiscal year.

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 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 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 are proposing a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. Although we are not proposing an additional prospective adjustment in FY 2014 for the cumulative MS–DRG documentation and coding effects through FY 2010, we are soliciting public comments as to whether any portion of the proposed −0.8 percent recoupment adjustment to the operating

IPPS standardized amount should be reduced and instead applied as a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS–DRG documentation and coding effect through FY 2010.

b. Proposed Refinement of the MS–DRG Relative Weight Calculation

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. To address the issue of charge compression (the hospital practice of applying higher charges to lower cost items and applying lesser charges to higher cost items) when using cost report data to set the MS–DRG relative weights, in FYs 2009 and 2010, we created additional cost centers on the Medicare cost report to distinguish implantable devices from other medical supplies, MRIs and CT scans, respectively, from other radiology services, and cardiac catheterization from other cardiology services. As compared to previous years, we currently have a significant volume of hospitals completing all, or some, of these new cost centers on the Medicare cost report. In section II.E. of the preamble of this proposed rule, we provide various data analyses based on comparison of the FY 2014 relative weights computed using 15 cost-to-charge ratios (CCRs), as we have done in the past, and the FY 2014 relative weights computed using 19 CCRs, with distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

We believe that the analytic findings described in section II.E. of the preamble of this proposed rule support our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we are proposing 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.

c. Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals

In section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the acute care hospital operating and capital market baskets used to update IPPS payment rates. For both market baskets, we are proposing to update the base year cost weights from a FY 2006 base year to a FY 2010 base year. We also are proposing to recalculate the labor-related share using the proposed FY 2010-based hospital market basket, for discharges occurring on or after October 1, 2013. We would use the FY 2010-based market basket in developing the FY 2014 update factor for the operating and capital prospective payment rates and the FY 2014 update factor for the excluded hospital rate-of-increase limits. We also are setting forth the data sources used to determine the proposed revised market basket relative weights.

d. Reduction of Hospital Payments for Excess Readmissions

We are proposing a number of changes in policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. 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. These conditions are acute myocardial infarction, heart failure, and pneumonia. For FY 2014, we are proposing additional exclusions to the three existing readmission measures (that is, the excess readmission ratio) that account for planned readmissions. We also are proposing additional readmission measures to be used in the payment determination for FY 2015. In addition, we are proposing that the readmissions payment adjustment factors for FY 2014 can be no more than a 2-percent reduction (there is a 1-percent cap in FY 2013), consistent with the statute. We are proposing a change in the methodology we use to calculate the readmissions payment adjustment factors to make it more consistent with the calculation of the excess readmission ratio.

e. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act 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. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

In this proposed rule, we are outlining payment details for the FY 2014 Hospital VBP Program. In addition, we are proposing numerous policies for the FY 2016 Hospital VBP Program, including measures, performance standards, and performance and baseline periods. We also are proposing a disaster/extraordinary circumstances waiver process, domain reclassification and weighting based on CMS' National Quality Strategy for the FY 2017 Hospital VBP Program, and certain measures, performance and baseline periods, and performance standards for the FY 2017 through FY 2019 Programs.

f. Hospital-Acquired Condition (HAC) Reduction Program

In this proposed rule, we are proposing measures, scoring, and risk adjustment methodology to implement the FY 2015 payment adjustment under the HAC Reduction Program. Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an adjustment to hospital payments for HACs, or a HAC Reduction program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce HACs, effective for discharges beginning on October 1, 2014 and for subsequent program years. 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.

g. Counting of Inpatient Days for Medicare Payment or Eligibility Purposes

In response to a comment we received on the FY 2013 IPPS/LTCH PPS final rule and consistent with the inpatient day counting rules for DSH as clarified in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we are proposing that patient days associated with maternity patients who were admitted as inpatients and were receiving ancillary labor and delivery services at the time the inpatient routine census is taken, regardless of whether the patient actually occupied a routine bed prior to occupying an ancillary labor and delivery bed and regardless of whether the patient occupies a ''maternity suite'' in which labor, delivery recovery, and postpartum care all take place in the same room, would be included in the Medicare utilization calculation. We understand that including labor and delivery inpatient days in the Medicare utilization calculation invariably would reduce direct GME payments because direct GME payments are based, in part, on a hospital's Medicare utilization ratio and the denominator of that ratio, which includes the hospital's total inpatient days, would increase at a higher rate than the numerator of the ratio, which includes the hospital's Medicare inpatient days. However, because the Medicare utilization ratio is a comparison of a hospital's *total*

Medicare inpatient days to its *total* inpatient days, we believe that revising the ratio to include labor and delivery days is appropriate because they are inpatient days and therefore should be counted as such. We are proposing to include labor and delivery days as inpatient days in the Medicare utilization calculation effective for cost reporting periods beginning on or after October 1, 2013.

h. Proposed Changes to the DSH Payment Adjustment and the Provision of 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. Currently, Medicare DSHs qualify for a DSH payment adjustment under a statutory formula that considers their Medicare utilization due to beneficiaries who also receive Supplemental Security Income benefits and their Medicaid utilization. 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 current statutory formula for Medicare DSH payments. 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 will receive its additional amount based on its share of the total amount of uncompensated care for all Medicare DSH hospitals for a given time period. In this proposed rule, we are proposing to implement these statutory changes.

i. Proposal Relating to Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A

To reduce uncertainty regarding the requirements for payments to hospitals and CAHs under Medicare Part A related to when a Medicare beneficiary should be admitted as a hospital inpatient, in this proposed rule, we are proposing to clarify the rules governing physician orders of hospital inpatient admissions for payment under Medicare Part A. We are proposing to clarify and specify in the regulations that an individual becomes an inpatient of a hospital, including a critical access hospital, pursuant to an order for inpatient admission by a physician or other qualified practitioner and, therefore, the order is required for payment of hospital inpatient services under Medicare Part A. We are proposing that hospital inpatient admissions spanning 2 midnights in the hospital would generally qualify as appropriate for payment under Medicare Part A. This would revise our guidance to hospitals and physicians relating to when hospital inpatient admissions are determined reasonable and necessary for payment under Part A. We also are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the additional IPPS expenditures under this proposal by reducing the standardized amount, the hospital-specific amount, and the Puerto Rico-specific standardized amount by 0.2 percent.

j. Proposed LTCH PPS Standard Federal Rate

In section VIII.A. of the preamble of this proposed rule, we present the proposed LTCH PPS standard Federal rate for FY 2014, which includes a proposed adjustment factor of 0.98734 for the second year of the 3-year phase-in of the permanent one-time adjustment to the standard Federal rate. In addition, under the LTCH Quality Reporting (LTCHQR) Program, the proposed annual update to the standard Federal rate will be reduced by 2 percentage points for LTCHs that fail to submit data for FY 2014 on specific measures under section 3004 of the Affordable Care Act.

k. Expiration of Certain Payment Rules for LTCH Services and Research on the Development of a Patient Criteria-Based Payment Adjustment Under the LTCH PPS

In section VIII.D. of the preamble of this proposed rule, we note the expiration of the moratorium on the full implementation of the ''25 percent threshold'' payment adjustment to LTCHs under the LTCH PPS for cost reporting periods beginning on or after October 1, 2013.

In section VIII.E. of the preamble of this proposed rule, we describe the results of research being done by a CMS contractor, Kennell and Associates (Kennell) and its subcontractor, Research Triangle Institute, International (RTI), on the development of a payment adjustment under the LTCH PPS based on the establishment of LTCH patient criteria.

l. 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 past rules, we have established measures for reporting and the process for submittal and validation of the data.

In this proposed rule, we are proposing to make several changes to: (1) The measure set, including the removal of some measures, the refinement of some measures, and the adoption of several new measures; (2) the administrative processes; and (3) the validation methodologies. We also are proposing to allow hospitals the option of reporting the measures in four measure sets electronically for the FY 2016 payment determination. These proposed changes would improve the timeliness and efficiency of the Hospital IQR Program and begin the process of incorporating electronic reporting into the Hospital IQR Program.

3. Summary of Costs and Benefits

- **Proposed Adjustment for MS–DRG Documentation and Coding Changes.** We are proposing a −0.8 percent recoupment adjustment to the standardized amount for FY 2014 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 Law110–90.

While our actuaries estimate 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, we are proposing a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We estimate that this level of adjustment would recover $0.96 billion in FY 2014, with approximately $10.4 billion remaining to be addressed. We are not proposing any future adjustments at this time but note that if recoupment adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, we estimate that the entire $11 billion will be recovered

by the end of the statutory 4-year timeline.

• **Proposed Refinement of the MS–DRG Relative Weight Calculation.** We refer readers to section VI.C. of Appendix A of this proposed rule for the overall IPPS operating impact, which includes the impact for the proposed refinement of the MS–DRG relative weight calculation. This proposed impact models payments to various hospital types using relative weights developed from 19 CCRs as compared to 15 CCRs. As with other proposed changes to the MS–DRGs, these proposed changes are to be implemented in a budget neutral manner.

• **Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals.** The proposed FY 2010-based IPPS market basket update (as measured by percentage increase) for FY 2014 is currently forecasted to be the same as the market basket update based on the FY 2006-based IPPS market basket at 2.5 percent (currently used under the IPPS). Therefore, we are projecting that there would be no fiscal impact on the IPPS operating payment rates in FY 2014 as a result of the proposed rebasing and revision of the IPPS market basket.

The proposed FY 2010-based IPPS capital input price index update (as measured by percentage increase) for FY 2014 is currently forecasted to be 1.2 percent, 0.2 percentage points lower than the update based on the FY 2006-based capital input price index. Therefore, we are projecting that there would be a fiscal impact of −$16 million to the IPPS capital payments in FY 2014 as a result of this proposal (0.2 percentage points * annual capital IPPS payments of approximately $8 billion).

In addition, we are proposing to update the labor-related share under the IPPS for FY 2014 based on the proposed FY 2010-based IPPS market basket, which would result in a labor-related share of 69.6 percent (compared to the FY 2013 labor-related share of 68.8) or 62 percent, depending on which results in higher payments to the hospital. For FY 2014, the proposed labor-related share for the Puerto Rico-specific standardized amount would be either 63.2 percent or 62 percent, depending on which results in higher payments to the hospital. We are projecting that there would be no impact on aggregate IPPS payments as a result of this proposal due to the statutory requirement that any changes to the IPPS area wage adjustment (including the labor-related share) are adopted in a budget neutral manner.

• **Reduction to Hospital Payments for Excess Readmissions.** The provisions of section 1886(q) of the Act which establishes the Hospital Readmissions Reduction Program are not budget neutral. For FY 2014, a hospital's readmissions payment adjustment factor is the higher of a ratio of a hospital's aggregate payments for excess readmissions to its aggregate payments for all discharges, or 0.98 (that is, or a 2-percent reduction). In this proposed rule, we estimate that the reduction to a hospital's base operating DRG payment amount to account for excess readmissions of selected applicable conditions under the Hospital Readmissions Reduction Program will result in a 0.2 percent decrease, or approximately −$175 million, in payments to hospitals for FY 2014.

• **Value-Based Incentive Payments Under the Hospital Value-Based Purchasing (VBP) Program.** We estimate that there will be no net financial impact to the Hospital VBP Program for FY 2014 in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given fiscal year must be equal to the total amount of base operating DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating DRG payment amount reductions for FY 2014, and therefore the estimated amount available for value-based incentive payments for FY 2014 discharges, is approximately $1.1 billion. We believe that the program's benefits will be seen in improved patient outcomes, safety, and in the patient's experience of care. We intend to provide an updated analysis of the program's estimated dollar impact for the FY 2014 program year in the FY 2014 IPPS/LTCH PPS final rule. However, we cannot estimate these benefits in actual dollar and patient terms.

• **Implementation of the HAC Reduction Program for FY 2014.** We note that there is no payment impact for FY 2014 for implementing the HAC Reduction Program. For FY 2015, we are presenting the overall impact of the HAC Reduction Program provision along with other IPPS payment provision impacts in section I.G. of Appendix A of this proposed rule.

• **Counting of Inpatient Days in the Medicare Utilization Calculation.** We believe our proposal to include labor and delivery days as inpatient days in the Medicare utilization calculation would result in a savings of approximately $15 million for FY 2014.

• **Changes to the Medicare DSH Payment Adjustment and Provision of Additional Payment for Uncompensated Care.** Under section 1886(r) of the Act (as added by section 3313 of the Affordable Care Act), disproportionate share payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment to eligible hospitals will be made 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. The remainder, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be the basis for additional payments 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 additonal payment based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

We are proposing that 75 percent of what otherwise would have been paid for Medicare DSH payments is adjusted to 88.8 percent of that amount for changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, Medicare DSH payments prior to the application of section 3133 are adjusted to 66.6 percent (the product of 75 percent and 88.8 percent) and that resulting payment amount is used to create an additional payment for a hospital's relative uncompensated care. As a result, we project that the reduction of Medicare DSH payments and the inclusion of the additional payments will reduce payments overall by 0.9 percent as compared to Medicare DSH payments prior to the implementation of section 3133. The proposed additional payment costs 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 tied to a hospital's discharges.

• **Proposal Relating to Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A.** In this proposed rule, we are making a proposal relating to admission and medical review criteria for hospital inpatient admissions under Medicare Part A. One aspect of this proposal is that hospital inpatient admissions spanning 2 midnights in the hospital would generally qualify as appropriate for payment under

Medicare Part A. Our actuaries estimate that the proposal would increase IPPS expenditures by approximately $220 million due to an expected net increase in inpatient encounters. We are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rate to offset this estimated $220 million in additional IPPS expenditures. We also are proposing to apply that 0.2 percent reduction to the capital Federal rates using our authority under section 1886(g) of the Act.

• **Hospital Inpatient Quality Reporting (IQR) Program.** We are proposing that hospitals participating in the Hospital IQR Program will have the option to report a subset of measures electronically in CY 2014 for the FY 2016 payment determination. Under this proposal, hospitals may choose to report the measures in four measure sets electronically or as chart-abstracted measures in CY 2014. For the FY 2016 payment determination, we also are proposing to remove seven chart-abstracted measures and one structural measure. We also are proposing to adopt five new claims-based measures for the FY 2016 payment determination and subsequent years. We are proposing, for the FY 2016 payment determination and subsequent years, to validate two additional chart-abstracted HAI measures: MRSA *bacteremia,* and *C. difficile.* We also are proposing to reduce the number of records used for HAI validation from 48 records per year to 36 records per year beginning with the FY 2015 payment determination. Finally, we are proposing to allow hospitals to submit patient charts for purposes of validation either in paper form or by means of electronic transmission. We believe the proposed changes to the measure set, processes, and validation methodologies, the proposal for electronic submission of records for validation, as well as the proposal to allow hospitals to report certain measures electronically for the FY 2016 payment determination will result in improved program efficiency and begin the process of incorporating electronic reporting into the program. We estimate that the combination of these proposed changes and the reduction in measures mentioned above will reduce burden hours by 700,000 hours annually.

• **Proposed Update to the LTCH PPS Standard Federal Rate and Other Payment Factors**. Based on the best available data for the 423 LTCHs in our database, we estimate that the proposed changes we are presenting in the preamble and Addendum of this proposed rule, including the proposed update to the standard Federal rate for FY 2014, the proposed changes to the area wage adjustment for FY 2014, and the proposed changes to short-stay outliers and high-cost outliers, would result in an increase in estimated payments from FY 2013 of approximately $62 million (or 1.1 percent). Although we generally project an increase in proposed payments for all LTCHs in FY 2014 as compared to FY 2013, we expect rural LTCHs to experience slightly lower increases than the national average due to decreases in their wage index for FY 2014 compared to FY 2013. In addition, under current law, our moratoria on the full implementation of the ''25-percent threshold'' payment adjustment policy will expire for certain LTCHs for cost reporting periods beginning on or after October 1, 2013. These regulatory moratoria extended, for an additional year, the 5-year statutory moratorium on the application of the ''25-percent threshold'' payment adjustment policy as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, which expired for cost reporting periods beginning on or after October 1, 2012 (''October LTCHs''), and for other LTCHs and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2012 (''July LTCHs'') (77 FR 53483 through 53484, as amended by the FY 2013 IPPS/LTCH PPS correcting amendment (77 FR 63751 through 63753)), as explained in section VIII.D. of the preamble of this proposed rule. We estimate that the expiration of the regulatory moratoria will result in a reduction in payments of $190 million to LTCHs. Overall, we estimate that the effect of the changes we are proposing for FY 2014 in conjunction with the expiration of the regulatory moratoria would result in a decrease in aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately −$128 million (that is, the estimated increase of $62 million plus the estimated reduction of $190 million, as described above).

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.

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. Through and including FY 2006, a Medicare-dependent, small rural hospital (MDH) received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. As discussed below, for discharges occurring on or after October 1, 2007, but before October 1, 2013, an MDH will receive 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. (We note that the statutory provision for payments to MDHs expires at the end of FY 2013, that is, on September 30, 2013.) SCHs are the sole source of care in their areas, and MDHs are a major source of care for Medicare beneficiaries 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. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries.

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; and cancer hospitals. 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, cancer hospitals, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR Parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR Part 412, Subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR Parts 413 and 415.

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. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148), the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), and the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

The Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, made a number of changes that affect the IPPS and the LTCH PPS. (Pub. L. 111–148 and Pub. L. 111–152 are collectively referred to as the ''Affordable Care Act.'') A number of

the provisions of the Affordable Care Act affect the updates to the IPPS and the LTCH PPS and providers and suppliers. The provisions of the Affordable Care Act that were applicable to the IPPS and the LTCH PPS for FYs 2010, 2011, and 2012 were implemented in the June 2, 2010 **Federal Register** notice (75 FR 31118), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50042) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51476).

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, also made a number of changes that affect the IPPS. We announced changes related to certain IPPS provisions for FY 2013 pursuant to sections 605 and 606 of Public Law 112–240 in a notice issued in the **Federal Register** on March 7, 2013 (78 FR 14689).

1. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)

In this proposed rule, we are proposing to implement, or continue in FY 2014 to implement, the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS, the LTCH PPS, and PPS-exempt cancer hospitals:

- Section 3001(a) of Public Law 111–148, which requires the establishment of a hospital inpatient value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards for the performance period for that fiscal year.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data by LTCHs in order for them to receive the full annual update to the payment rates beginning with the FY 2014 rate year.
- Section 3005 of Public Law 111–148, which provides for the establishment of a quality reporting program for PPS-exempt cancer hospitals beginning with FY 2014, and for subsequent program years.
- Section 3008 of Public Law 111–148, which establishes the Hospital-Acquired Condition (HAC) Reduction Program and requires the Secretary to make an adjustment to hospital payments for applicable hospitals, effective for discharges beginning on October 1, 2014, and for subsequent program years.
- Section 3025 of Public Law 111–148, which establishes a hospital readmissions reduction program and requires the Secretary to reduce payments to applicable hospitals with excess readmissions effective for discharges beginning on or after October 1, 2012.
- Section 3133 of Public Law 111–148, which modifies the methodologies for determining Medicare DSH payments and creates a new additional payment for uncompensated care.
- Section 3401 of Public Law 111–148, which provides for the incorporation of productivity adjustments into the market basket updates for IPPS hospitals and LTCHs.
- Section 10324 of Public Law 111–148, which provides for a wage adjustment for hospitals located in frontier States.
- Sections 3401 and 10319 of Public Law 111–148 and section 1105 of Public Law 111–152, which revise certain market basket update percentages for IPPS and LTCH PPS payment rates for FY 2014.
- Section 5506 of Public Law 111–148, which added a provision to the Act that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the aggregate number of FTE resident cap slots distributed is equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively.

2. American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

In this proposed rule, we are proposing to implement or to make conforming changes to regulation text in accordance with the following provisions (or portions of the following provisions) of the American Taxpayer Relief Act of 2012 that are applicable to the IPPS:

- Section 605, which amended sections 1886(d)(12)(B), (C)(i), and (D) of the Act to extend changes to the payment methodology for the Medicare inpatient hospital payment adjustment for low-volume hospitals through September 30, 2013 (FY 2013). Beginning with FY 2014, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.
- Section 606(a), which amended sections 1886(d)(5)(G)(i) and (ii)(II) of the Act to extend the MDH program through September 30, 2013 (FY 2013), and section 606(b), which made conforming amendments to sections 1886(b)(3)(D)(i) and (iv) of the Act and amended section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 to permit hospitals to decline reclassification through FY 2013.
- Section 631, 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).

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals in FY 2014. We also are setting forth proposed changes relating to payments for IME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in this proposed rule, we are setting forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2014.

Below is a summary of the major changes that we are proposing to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review.
- Proposed application of the documentation and coding adjustment for FY 2014 resulting from implementation of the MS–DRG system.
- A discussion of the Research Triangle Institute, International (RTI) reports and recommendations relating to charge compression, including the proposal to calculate the MS–DRG relative weights using 19 CCRs.
- Proposed recalibrations of the MS–DRG relative weights.
- Proposed changes to hospital-acquired conditions (HACs) and a listing and discussion of HACs, including infections, that would be subject to the statutorily required adjustment in MS–DRG payments for FY 2014.
- A discussion of the FY 2014 status of new technologies approved for add-on payments for FY 2013 and a presentation of our evaluation and analysis of the FY 2014 applicants for add-on payments for high-cost new medical services and technologies

(including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include the following:

- The proposed FY 2014 wage index update using wage data from cost reporting periods beginning in FY 2010.
- Analysis and implementation of the proposed FY 2014 occupational mix adjustment to the wage index for acute care hospitals, including the proposed application of the rural floor, the imputed rural floor calculated under the original and alternative methodologies, and the frontier State floor.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.
- The proposed adjustment to the wage index for acute care hospitals for FY 2014 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- The timetable for reviewing and verifying the wage data used to compute the proposed FY 2014 hospital wage index.
- Determination of the labor-related share for the proposed FY 2014 wage index.

3. Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals

In section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the acute care hospital operating and capital market baskets to be used in developing the FY 2014 update factor for the operating and capital prospective payment rates and the FY 2014 update factor for the excluded hospital rate-of-increase limits. We also are setting forth the data sources used to determine the proposed revised market basket relative weights.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section V. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR Parts 412 and 413, including the following:

- Proposed changes to the inpatient hospital update for FY 2014, including incorporation of a productivity adjustment.
- The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2014.
- The statutorily required IME adjustment factor for FY 2014.
- Proposed changes to the methodologies for determining Medicare DSH payments and proposals to implement the new additional payments for uncompensated care.
- Discussion of the extension of the MDH program through FY 2013.
- Proposed changes to the rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates.
- 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.
- Proposal for counting labor and delivery inpatient days in the calculation of Medicare utilization for direct GME purposes and for other inpatient days policy for payments and eligibility.
- Announcement of an additional closed hospital and redistribution of resident cap slots relating to direct GME and IME payments.
- Proposed clarifications of policies on payments for residents training in approved residency programs at CAHs.
- Announcement of the expiration of the inflation update freeze for high per resident amounts (PRAs).
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Extending the effective date of policies relating to hospital services furnished under arrangements.
- Proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 midnights) in the hospital receiving medically necessary services.

5. Proposed FY 2014 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2014 and other related proposed policy changes.

6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of this proposed rule, we discuss—

- Proposed changes to payments to certain excluded hospitals for FY 2014.
- Proposed changes to the conditions of participation (CoPs) relating to administration of pneumococcal vaccine and CAH payment for acute care inpatient services.

7. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of this proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2014. We also note that the moratorium on the full implementation of the ''25-percent threshold'' payment adjustment will expire for certain cost reporting periods beginning on or after October 1, 2013. In addition, in this section, we describe the results of research being done by Kennell and Associates (Kennell) and its subcontractor, Research Triangle Institute, International (RTI), under a contract with CMS on the development of a payment adjustment under the LTCH PPS based on the establishment of LTCH patient criteria.

8. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of this proposed rule, we address—

- 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 (LTCHQR) Program.
- Proposed changes to the requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.

9. Determining Proposed Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2014 prospective payment rates for operating costs and

capital-related costs for acute care hospitals. We are proposing to establish the threshold amounts for outlier cases. In addition, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2014 for certain hospitals excluded from the IPPS.

10. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2014 prospective standard Federal rate. We are proposing to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

11. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, LTCHs, PCHs, and IPFs.

12. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2014 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 rate for hospital inpatient services furnished by LTCHs.

13. 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 2013 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs under the IPPS, for hospitals and distinct part hospital units excluded from the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2013 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*.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

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), and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. Proposed FY 2014 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. (Currently, there are 751 MS–DRGs.) 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, Public Law 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 (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 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 precisely 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 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 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 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 for $3,655 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 1.054 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 believe 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 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 note that, as a result, payments in FY 2011 (and in each future 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 will 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 to partially eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments.

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 believe 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 years until a full adjustment is made.

We note 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 as 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

As discussed in section II.D.3. of this preamble, 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 this 5.8 percentage point increase resulted 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 rate adjustments over more than one year in order to moderate the effect on 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 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, any adjustment made to reduce rates in one year would eventually be offset by a positive adjustment, once the necessary amount of overpayment is recovered.

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. In its March 2013 ''Report to Congress: Medicare Payment Policy,'' MedPAC estimates that a −2.4 percent adjustment made in FY 2014, and not removed until FY 2018, also would recover the required recoupment amount. It is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we are proposing a −0.8 percent recoupment adjustment to the

standardized amount in FY 2014. We estimate that this level of adjustment will recover up to $0.96 billion in FY 2014, with at least $10.04 billion remaining to be recovered by FY 2017. 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 are not proposing specific adjustments for FYs 2015, 2016, or 2017 at this time. We believe that this level of adjustment for FY 2014 is a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates. We again note that this −0.8 percent recoupment adjustment, and future adjustments under this authority, will be eventually offset by an equivalent positive adjustment once the full $11 billion recoupment requirement has been realized.

7. Additional Prospective Adjustments for the MS–DRG Documentation and Coding Effect Through FY 2010 Authorized 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 if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case-mix. After review of comments and recommendations received in a FY 2012 public comment letter from MedPAC (available on the Internet at: *http://www.medpac.gov/documents/06172011_FY12IPPS_MedPAC_COMMENT.pdf*), we analyzed claims data in FY 2010 to determine whether any additional adjustment would be appropriate to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. We analyzed FY 2010 data on claims paid through December 2011 using the same claims-based methodology as described in previous rulemaking (73 FR 43768 and 43775). We determined a total additional prospective documentation and coding effect of 0.8 percent through FY 2010 and found that this effect was present for both IPPS hospitals paid with the standardized amount and IPPS hospitals paid using their hospital-specific payment rates.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27890), we proposed an additional −0.8 percent prospective adjustment to the standardized amount to account for this effect. We indicated that this additional prospective adjustment of −0.8 percent, when combined with the other prospective MS–DRG documentation and coding adjustments already made or proposed would eliminate the future effect of MS–DRG documentation and coding that did not reflect real changes in case-mix for discharges occurring through FY 2010. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53278 through 53280), numerous commenters objected to the CMS proposal to make an adjustment to account for payment increases due to MS–DRG documentation and coding that did not reflect real changes in case-mix for discharges occurring through FY 2010. Many commenters continued to assert that our estimates of documentation and coding were overstated, and could be explained by other factors. These commenters also focused on part of the analysis provided by MedPAC in its FY 2012 public comment letter indicating that a slightly smaller additional prospective adjusment of −0.55 percent rather than −0.8 percent might be required to offset the cumulative MS–DRG documentation and coding effect through FY 2010. Specifically, while MedPAC supported the overall methodology, it suggested that it was possible that changes in documentation and coding to optimize payments under the MS–DRG GROUPERs and weights may have resulted in slightly less than optimal payments under the FY 2007 GROUPER and weights (the denominator of the documentation and coding change estimate). Many commenters requested that, given the MedPAC analysis, if CMS were to apply an additional prospective adjustment to the MS–DRG documentation and coding effect through FY 2010, it should subtract 0.25 percentage points from its estimate, for an adjustment of −0.55 percent.

After considering the public comments, we recognized that the issue of the estimate to use for the cumulative MS–DRG documentation and coding effect through FY 2010 may merit further consideration. Therefore, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53278 through 53280), we decided not to finalize the proposed −0.8 percent adjustment to the standardized amount and the hospital-specific rate until more analysis could be completed.

CMS is continuing to consider whether MedPAC's recommendation that an adjustment to offset the cumulative documentation and coding effects through FY 2010 under section 1886(d)(3)(A)(vi) of the Act is appropriate and supported by a review of the claims data. After further consideration of the MedPAC analysis and the request by many public commenters, if we were to apply an additional prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010, we believe the most appropriate additional adjustment is −0.55 percent.

It is often our practice to delay or phase-in adjustments to mitigate negative financial impacts. Because we are proposing a −0.8 percent recoupment adjustment, as discussed in section II.D.6. of the preamble of this proposed rule, we are not proposing a prospective adjustment in FY 2014 for the cumulative MS–DRG documentation and coding effect through FY 2010. However, we are soliciting public comments as to whether any portion of the proposed −0.8 percent recoupment adjustment should be reduced and instead applied to a prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010. For example, we could apply a −0.25 percent recoupment adjustment, and a −0.55 prospective adjustment, for a total FY 2014 adjustment of −0.8 percent. Reducing the recoupment adjustment in FY 2014 would require relatively larger adjustments for FYs 2015, 2016, and/or 2017, but making a prospective adjustment of −0.55 percent would eliminate future payment increases due to MS–DRG documentation and coding that did not reflect real changes in case-mix for discharges occurring through FY 2010. As we discuss above, because the documentation and coding effect through FY 2010 was found for both IPPS hospitals paid with the standardized amount and IPPS hospitals paid under their hospital-specific payment rate, if we were to apply a prospective adjustment to remove this effect, we also would apply such an adjustment to the hospital-specific payment rate, using the Secretary's broad authority under section 1886(d)(5)(I)(i) of the Act (77 FR 53276 through 53277). Therefore, if we attribute a portion of the −0.8 percent adjustment for FY 2014 to the prospective adjustment, we also would make appropriate adjustments to the hospital-specific payment rates. Puerto Rico-specific rates would not be affected, as we previously found no significant additional MS–DRG documentation and coding effect for FY 2010 that would warrant any additional

adjustment to the Puerto Rico-specific rate (77 FR 53279).

E. Proposed 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 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 cost-to-charge ratios (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/LTCH PPS 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/LTCH PPS 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 report 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 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.

2. Discussion and Proposal for FY 2014

To calculate the proposed FY 2014 MS–DRG relative weights, we are proposing to continue our current methodology of using the two most recent data sources: the December 2012 update of the FY 2012 MedPAR file as the claims data source and the December 2012 update of FY 2011 HCRIS as the cost data source. We currently have 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. Specifically, using the December 2012 update of FY 2011 HCRIS, we were able to calculate a valid implantable device CCR for 2,285 IPPS hospitals, a valid MRI CCR for 1,402 IPPS hospitals, a valid CT scan CCR for 1,470 IPPS hospitals, and a valid cardiac catheterization CCR for 1,022 IPPS hospitals. 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.

We believe that there is a sufficient amount of data in the FY 2011 cost reports from which to generate a meaningful analysis of using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. In addition, the corresponding charge data on hospital claims for implantable devices, MRIs, CT scans, and cardiac catheterization are available in the FY 2012 MedPAR file. Therefore, we are providing various data analyses below based on comparison of the FY 2014 relative weights computed using 15 CCRs, as we have done in the past, and the FY 2014 relative weights computed using 19 CCRs, with distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Specifically, rather than having a single CCR for ''Supplies and Equipment'' which includes low-cost supplies and high-cost implantable devices, a distinct CCR would be carved out of the ''Supplies and Equipment'' CCR, leaving one CCR for ''Supplies'' and one CCR for ''Implantable Devices.'' Regarding the Radiology CCR, which currently is comprised of general radiology ancillary services and MRIs and CT scans, the costs for MRIs and CT scans would be separated from general radiology, creating two distinct CCRs, one for MRIs and one for CT scans, respectively. Finally, by separating the costs of cardiac catheterization out of the CCR for general cardiology, a distinct CCR would be created for cardiac catheterization. Thus, by breaking out these 4 additional CCRs, the number of CCRs used to calculate the relative weights would increase from 15 to 19.

For comparison purposes, the following table shows the final FY 2013 CCRs, the potential FY 2014 CCRs computed with the existing 15 cost centers, and the potential FY 2014 CCRs computed with 19 cost centers, with 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

Group	Final FY 2013 15 CCRs	Potential FY 2014 15 CCRs	Potential FY 2014 19 CCRs
Routine days	0.514	0.502	0.502
Intensive days	0.442	0.423	0.423
Drugs	0.199	0.193	0.193
Supplies & Equipment	0.335	0.327	0.293
Implantable Devices	n/a	n/a	0.361
Therapy Services	0.370	0.355	0.355
Laboratory	0.143	0.133	0.133
Operating Room	0.238	0.225	0.225
Cardiology	0.145	0.134	0.132
Cardiac Catheterization	n/a	n/a	0.135
Radiology	0.136	0.128	0.170
MRI	n/a	n/a	0.091
CT Scans	n/a	n/a	0.045
Emergency Room	0.226	0.207	0.207
Blood	0.389	0.371	0.371
Other Services	0.397	0.399	0.399
Labor & Delivery	0.450	0.445	0.445
Inhalation Therapy	0.189	0.187	0.187
Anesthesia	0.109	0.120	0.120

In order to model the effects on the relative weights in medical MS–DRGs versus surgical MS–DRGs, we compared a set of relative weights calculated with 15 CCRs and 19 CCRs. Overall, if 19 CCRs are used to calculate the relative weights for FY 2014, relative weights for medical MS–DRGs would be expected to decrease by approximately 1.1 percent, and those for surgical MS–DRGs would be expected to increase by approximately 1.2 percent. In addition, as shown in the table below, at the MDC level, payments would increase by approximately 0.64 percent (0.39 + 0.25) within orthopedic and cardiac MDCs, with most of the reductions in payment resulting to the medical MS–DRGs in

the nervous system, digestive system, and respiratory system MDCs.

MDC	Description	Estimated percentage change within MDC (percent)
08	Musculoskeletal System and Connective Tissue	0.39
05	Circulatory System	0.25
01	Nervous System	−0.16
06	Digestive System	−0.10
04	Respiratory System	−0.08

The largest estimated increase in MS–DRG relative weights would likely occur for MS–DRGs associated with cardiac catheterization and implantable cardiac devices. The largest estimated reductions in MS–DRG relative weights would likely occur for MS–DRGs associated with traumatic head injury and concussion, which are high users of CT scanning and MRI services. We are including in the table below the top 10 (nonlabor and delivery) MS–DRGs that we predict would experience the largest increases and decreases in relative weights if 19 CCRs would be used as compared to 15 CCRs.

MS–DRG	Type	Title	Potential relative weight with 15 CCRs	Potential relative weights with 19 CCRs	Percentage change
MS–DRGs that would experience the largest decrease in relative weight					
090	MED	Concussion without CC/MCC	0.7614	0.7013	−7.9
084	MED	Traumatic Stupor & Coma, Coma >1 Hour without CC/MCC	0.9137	0.8516	−6.8
087	MED	Traumatic Stupor & Coma, Coma <1 Hour without CC/MCC	0.7899	0.7369	−6.7
965	MED	Other Multiple Significant Trauma without CC/MCC	1.0450	0.980	−6.1
185	MED	Major Chest Trauma without CC/MCC	0.7281	0.6845	−6.0
089	MED	Concussion with CC	0.9959	0.9366	−6.0
123	MED	Neurological Eye Disorder	0.7355	0.6920	−5.9
343	SURG	Appendectomy without Complicated Principal Diagnosis without CC/MCC	0.9880	0.9517	−5.7
053	MED	Spinal Disorders & Injuries without CC/MCC	0.9355	0.8825	−5.7
066	MED	Intracranial Hemorrhage or Cerebral Infarction without CC/MCC	0.8034	0.7579	−5.7
MS–DRGs that would experience the largest increase in relative weight					
454	SURG	Combined Anterior/Posterior Spinal Fusion with CC	7.6399	8.0563	5.5
455	SURG	Combined Anterior/Posterior Spinal Fusion Without CC/MCC	5.9862	6.3133	5.5
484	SURG	Major Joint & Limb Reattachment Procedure of Upper Extremity without CC/MCC.	2.1211	2.2380	5.5
225	SURG	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC.	5.6298	5.9530	5.7
223	SURG	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC.	6.0956	6.4482	5.8
458	SURG	Spinal Fusion Except Cervical with Spinal Curve/Malignant/Infection OR 9+ Fusion without CC/MCC.	4.8794	5.1630	5.8
245	SURG	AICD Generator Procedures	4.4627	4.7320	6.0
849	MED	Radiotherapy	1.3423	1.4258	6.2
946	MED	Rehabilitation without CC/MCC	1.1295	1.2024	6.5
227	SURG	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	5.2193	5.5714	6.7

After computing the analyses described above by comparing both sets of MS–DRG relative weights computed with FY 2011 cost report data, we revisited RTI's July 2008 final report. We note that the impacts on relative weight and at the MDC level are generally consistent with those estimated by RTI in its modeling. RTI found that disaggregating the CCRs for medical supplies and devices would have the most impact on reducing charge compression, and that the largest impact was for MS–DRG 227. Similarly, as shown in the chart above, we estimate that the potential relative weight for MS–DRG 227 would experience the largest increase, 6.7 percent. Cardiac implants and spinal fusion procedures accounted for most of the 10 MS–DRGs with the largest incremental increases. In addition, RTI's July 2008 final report (pages 103 through 107) indicates that among the largest expected reductions are the MS–DRG relative weights for MS–DRGs associated with traumatic head injury and concussion, which are high users of CT scanning and MRI services. RTI's analyses were highly predictive for many of the MS–DRGs most sensitive to the effects of charge compression.

As we have stated in prior rulemaking (77 FR 53281 through 53283), once we determined that cost report data were available for analysis, we would propose, if appropriate, to use the distinct CCRs described above in the calculation of the MS–DRG relative weights. We believe that the analytic findings described above using the FY 2011 cost report data and FY 2012

claims data support our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we see no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we are proposing 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 welcome public comments on this proposal and the impacts that it may have. We refer readers to section VI.C. of Appendix A of this proposed rule for the overall IPPS operating impact of this proposal, which models payments to various hospital types using relative weights developed from 19 CCRs as compared to 15 CCRs. In addition, each year, as part of the IPPS proposed rule and final rule, we issue Table 5, which lists all of the MS–DRGs and their relative weights. As part of this FY 2014 IPPS/LTCH PPS proposed rule, in addition to providing Table 5, which lists the proposed MS–DRGs and their relative weights using 19 CCRs (available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp*; click on the link on the left side of the screen titled ''FY 2014 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''), we are providing a separate table that lists all MS–DRGs and their relative weights if computed using 15 CCRs (available at the same CMS Web site cited above). These two formats will allow readers to compare our proposal to calculate the MS–DRG relative weights using 19 CCRs with the relative weights of MS–DRGs if computed using 15 CCRs.

F. Adjustment to MS–DRGs for Preventable Hospital-Acquired Conditions (HACs), Including Infections

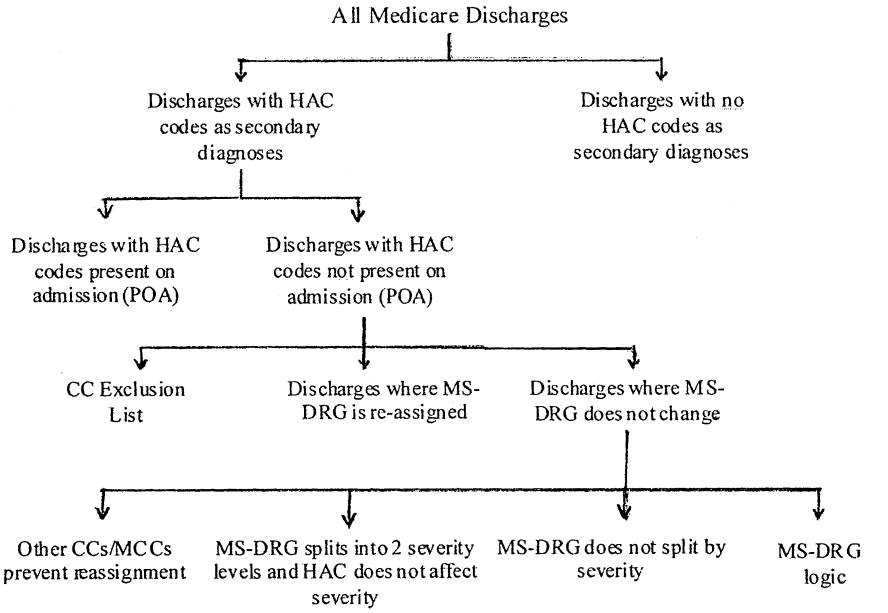
1. Background

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 certain 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. 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 CC or an MCC. The presence of a CC or an MCC generally results in a higher payment.

Section 1886(d)(4)(D) 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 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, pursuant to 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/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.



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); and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53283 through 53303). A complete list of the 11 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 discussed in the prior rulemaking cited above, the POA indicator reporting requirement only applies to IPPS hospitals because they are subject to this HAC provision. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, hospitals in Maryland operating under waivers, RNHCIs, and the Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting. We note that hospitals in Maryland operating under their waiver are not paid under the IPPS but rather are paid under the provisions of section 1814(b)(3) of the Act. This waiver applies to the amount paid to providers of services, and does not extend to billing requirements and other reporting requirements. In fact, hospitals in Maryland are required to submit Medicare claims for Medicare payment and also to submit the same information on their Medicare claims as hospitals in other parts of the country paid under the IPPS. Therefore, we believe it is inappropriate to continue to exempt hospitals in Maryland from the POA indicator reporting requirement. Under current policy, hospitals in Maryland will continue to be exempt from the application of this HAC provision so long as they are not paid under the IPPS. However, we believe it is appropriate to require them to use POA indicator reporting on their claims so that we can include their data and have as complete a dataset as possible when we analyze trends and make further payment policy determinations, such as those authorized under section 1886(p) of the Act. (We refer readers to section V.I. of the preamble to this proposed rule for a discussion of our proposals to implement section 1886(p) of the Act.) Therefore, we are proposing that hospitals in Maryland operating under their waiver under section 1814(b)(3) of the Act will no longer be exempted from the POA indicator reporting requirement beginning with claims submitted on or after October 1, 2013, including all claims for discharges on or after October 1, 2013. We are inviting public comment regarding this proposal.

As discussed in previous IPPS proposed and final rules, there are five POA indicator reporting options, as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting.* Under the HAC 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/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/MCC level. We refer readers to the following rules for a detailed discussion: 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); and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27893 through 27894) and final rule (77 FR 53284 through 53285).

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.
1	Signifies exemption from POA reporting. CMS established this code as a workaround to blank reporting on the electronic 4010A1. A list of exempt ICD–9–CM diagnosis codes is available in the *ICD–9–CM Official Guidelines for Coding and Reporting.*

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 have 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*.

In addition, as discussed elsewhere in section III.G.10. of the preamble of this proposed rule, 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 and all secondary diagnoses up to 25.

4. HACs and POA Reporting in ICD–10–CM and ICD–10–PCS

As we stated 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, 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 will 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 current ICD–9–CM selected HACs has 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 current selected HACs available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. The translations can be found under the link titled ''ICD–10–CM/PCS MS–DRG v30 Definitions Manual Table of Contents—Full Titles—HTML Version in Appendix I—Hospital Acquired Conditions (HACs).'' The above CMS Web site regarding the ICD–10–MS–DRG Conversion Project is also available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html*. We encourage 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 has been set up for this purpose under the Related Links section titled ''CMS HAC Feedback.'' The final HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS will be subject to formal rulemaking.

In the meantime, we continue to encourage readers to review the educational materials and draft code sets currently available for ICD–10–CM/ICD–10–PCS on the CMS Web site at: *http://www.cms.gov/ICD10/*. In addition, the draft ICD–10–CM/ICD–10–PCS coding guidelines can be viewed on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm*.

5. Proposals Regarding Current HACs and Previously Considered Candidate HACs

We are not proposing to add or remove categories of HACs at this time. However, we continue to encourage public dialogue about refinements to the HAC list by written stakeholder comments about both previously selected and potential candidate HACs. We 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 these conditions. We also refer readers to section III.F.5. of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53285 through 53292) for the HAC policy for FY 2013. In addition, readers may find updated information on evidence-based guidelines on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html*.

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 MedPAR 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 MedPAR claims data, RTI also conducted analyses on readmissions due to HACs, the incremental costs of HACs to the healthcare 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. Current and Previously Considered Candidate HACs—RTI Report on Evidence-Based Guidelines

The RTI program evaluation includes a report that provides references for all evidence-based guidelines available for each of the selected and previously considered candidate HACs that provide 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.

Evidence-based guidelines that included specific recommendations for the prevention of the condition were identified for each of the selected conditions. In addition, evidence-based guidelines also were found for the previously considered candidate conditions. RTI prepared a final report to summarize its findings regarding evidence-based guidelines. This report can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html*. Subsequent to this final report, RTI has been awarded an FY 2014 Evidence-Based Guidelines Monitoring contract. Under the contract, RTI will provide a summary report of all evidence-based guidelines available for each of the selected and previously considered candidate HACs that provide recommendations for the prevention of the corresponding conditions. Updates to the guidelines will be made available to the public.

G. Proposed Changes to Specific MS–DRG Classifications

In this FY 2014 IPPS/LTCH PPS proposed rule, we are inviting public comment 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 are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data.

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by early December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2014, comments and suggestions should have been submitted by early December 2012. The comments that were submitted in a timely manner are discussed below in this section.

1. Pre-Major Diagnostic Categories (Pre-MDCs): Heart Transplants and Liver Transplants

We received a request from an organization that represents transplant surgeons to eliminate the severity levels for the heart and liver transplants MS–DRGs. The MS–DRGs for heart transplants are: MS–DRG 001 (Heart Transplant or Implant of Heart Assist System with MCC) and MS–DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC). The MS–DRGs for liver transplants are: MS–DRG 005 (Liver Transplant with MCC or Intestinal Transplant) and MS–DRG 006 (Liver Transplant without MCC). We received this comment during the comment period for the FY 2013 IPPS/LTCH PPS proposed rule. We referred to this comment briefly in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53325), but we did not address the issue because we considered this comment outside of the scope of the proposed rule. However, we are addressing this issue in this FY 2014 proposed rule.

The commenter stated that there are no ''uncomplicated'' heart transplants or liver transplants, and indicated that all of these transplant procedures are highly complex, involving numerous complicating conditions, only some of which may be recognized by the MS–DRGs. The commenter expressed concern that the continued bifurcation of the MS–DRGs for heart and liver transplants will result in unsustainable payment for these cases that are assigned to the ''without MCC'' MS–DRGs 002 and 006. According to the commenter, in light of the relatively small number of Medicare patients involved and the significant cost variation involved, it would be preferable to eliminate the bifurcation of these procedures, thereby increasing the stability of the DRG weights for these procedures.

We examined claims data from the FY 2012 MedPAR file for heart and liver transplant cases assigned to MS–DRGs 001, 002, 005, and 006. The following table illustrates our findings:

MS–DRGs	Number of cases	Average length of stay	Average costs
MS–DRG 001	1,247	33.27	$158,556
MS–DRG 002	284	18	97,932
MS–DRGs 001 and 002—All cases	1,531	30.4	147,310
MS–DRG 005	828	19	66,746
MS–DRG 006	282	8.75	30,873
MS–DRGs 005 and 006—All cases	1,110	16.3	57,632

The data showed that the majority of the heart transplant cases, a total of 1,247, are assigned to MS–DRG 001, with average costs of approximately $158,556 and an average length of stay of approximately 33.27 days. There were 284 cases assigned to MS–DRG 002, with average costs of approximately $97,932 and an average length of stay of approximately 18 days.

This table shows that there are significant differences in average lengths of stay and average costs for the severity level for the heart transplant MS–DRGs that justify the existing split in MS–DRGs 001 and 002. If we were to combine the heart transplant cases in MS–DRGs 001 and 002 as suggested by the commenter, the payment for the majority of cases with an MCC would be lower.

The majority of the liver transplant cases, 828 cases, were assigned to MS–DRG 005, with average costs of approximately $66,746 and an average length of stay of approximately 19 days. There were 282 cases assigned to MS–DRG 006, with average costs of approximately $30,873 and an average length of stay of approximately 8.75 days. The data showed that there are significant differences in average costs and average lengths of stay in the severity levels for the liver transplant MS–DRGs. Again, if we were to combine all the liver transplant cases into one MS–DRG as requested by the commenter, the majority of the cases would receive lower payment.

Based on these findings, we believe that it would not be prudent to eliminate the severity levels for the heart and liver transplant MS–DRGs. Our clinical advisors concur with this analysis that two severity levels are justified for the heart and liver transplant MS–DRGs. Therefore, for FY 2014, we are not proposing to make any changes to the severity levels for heart and liver transplant MS–DRGs 001, 002, 005, and 006.

We are inviting public comments on this issue.

2. MDC 1 (Diseases and Disorders of the Nervous System): Tissue Plasminogen Activator (tPA) (rtPA) Administration Within 24 Hours Prior to Admission

During the comment period for the FY 2013 IPPS/LTCH PPS proposed rule, we received a public comment that we considered to be outside the scope of that proposed rule. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53325) that we would consider this issue in future rulemaking as part of our annual review process. The commenter requested that CMS conduct an analysis of diagnosis code V45.88 (Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility). Diagnosis code V45.88 was created for use beginning October 1, 2008, to identify patients who are given tissue plasminogen activator (tPA) at one institution and then transferred and admitted to a comprehensive stroke center for further care. This situation has been referred to as the ''drip-and-ship'' issue and was discussed at length in the FY 2009 IPPS proposed rule (73 FR 23563 through 23564) and final rule (73 FR 48493 through 48495), as well as the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23899 through 23900) and final rule (75 FR 50102 through 50106). We refer readers to these previous discussions for detailed background information regarding this topic.

Similar to previous requests, according to the commenter, the concern at the receiving facilities is that the costs associated with [caring for] more complex stroke patients that receive tPA are much higher than the cost of the drug, presumably because stroke patients initially needing tPA have more complicated strokes and outcomes. However, because these patients do not receive the tPA at the second or transfer hospital, the receiving hospital will not be able to assign the case to one of the higher-weighted tPA stroke MS–DRGs when it admits these patients whose care requires the use of intensive resources. The MS–DRGs that currently include the diagnosis code for the use of tPA are: MS–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC); MS–DRG 062 (Acute Ischemic Stroke with Use of Thrombolytic Agent with CC); and MS–DRG 063 (Acute Ischemic Stroke with Use of Thrombolytic Agent without CC/MCC). These MS–DRGs have higher relative weights than the other MS–DRGs relating to stroke or cerebral infarction. The commenter requested an analysis of diagnosis code V45.88 to determine whether new claims data warrant any change in the MS–DRG structure.

For this proposed rule, we analyzed MedPAR claims data from FY 2012. We included claims for patient cases assigned to the following MS–DRGs:

- 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC)
- 062 (Acute Ischemic Stroke with Use of Thrombolytic Agent with CC)
- 063 (Acute Ischemic Stroke with Use of Thrombolytic Agent without CC/MCC)
- 064 (Intracranial Hemorrhage or Cerebral Infarction with MCC)
- 065 (Intracranial Hemorrhage or Cerebral Infarction with CC)
- 066 (Intracranial Hemorrhage or Cerebral Infarction without CC/MCC).

Our data analysis included MS–DRGs 064, 065, and 066 because claims involving diagnosis code V45.88 also would be properly reported in the data for these MS–DRGs. The following table reflects the results of our analysis of the MedPAR data in which diagnosis code V45.88 was reported as a secondary diagnosis for FY 2012.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 061—All cases	3,369	7.48	$18,556
MS–DRG 061—Cases with secondary diagnosis code V45.88	140	7.51	19,008
MS–DRG 062—All cases	5,277	4.92	12,935
MS–DRG 062—Cases with secondary diagnosis code V45.88	179	5.03	13,317
MS–DRG 063—All cases	1,709	3.45	10,363
MS–DRG 063—Cases with secondary diagnosis code V45.88	48	3.15	9,372
MS–DRG 064—All cases	64,095	6.30	11,654
MS–DRG 064—Cases with secondary diagnosis code V45.88	955	7.06	14,432
MS–DRG 065—All cases	101,011	4.29	7,414
MS–DRG 065—Cases with secondary diagnosis code V45.88	1,259	4.91	9,471
MS–DRG 066—All cases	56,620	2.92	5,414
MS–DRG 066—Cases with secondary diagnosis code V45.88	493	3.28	6,682

Based on our review of the data for all of the cases in MS–DRGs 064, 065, and 066, compared to the subset of cases containing diagnosis code V45.88 as the secondary diagnosis, we again concluded that the movement of cases with diagnosis code V45.88 as a secondary diagnosis from MS–DRGs 064, 065, and 066 to MS–DRGs 061, 062, and 063 is not warranted. We determined that the differences in the average lengths of stay and the average costs are too small to warrant an assignment to the higher-weighted MS–DRGs.

However, the data does reflect that the average costs for cases reporting diagnosis code V45.88 as a secondary diagnosis in MS–DRG 066 are more similar to the average costs of higher

severity level cases in MS–DRG 065. Therefore, for FY 2014, we are proposing to move cases with diagnosis code V45.88 from MS–DRG 066 to MS–DRG 065, and to revise the title of MS–DRG 065 to reflect the patients status post tPA administration within 24 hours. The proposed revised MS–DRG title would be: MS–DRG 065 (Intracranial Hemorrhage or Cerebral Infarction with CC or tPA in 24 Hours).

We are inviting public comments on our proposal.

3. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)

a. Endoscopic Placement of a Bronchial Value

In response to the FY 2013 IPPS/LTCH PPS proposed rule, we received a request to modify the MS–DRG assignment for bronchial valve(s) insertion, which we considered to be outside of the scope of that proposed rule (77 FR 53325 through 53326). The requestor asked that cases in MS–DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, and without MCC/CC, respectively) that involve insertion of a bronchial valve be assigned instead to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without MCC/CC, respectively). The procedures are captured by procedure codes 33.71 (Endoscopic insertion or replacement of bronchial valve(s), single lobe) and 33.73 (Endoscopic insertion or replacement of bronchial valve(s), multiple lobes), which are considered nonoperating procedures and do not affect the MS–DRG assignment. When reported without any other operating room (OR) procedure code, the admission would be assigned to a medical MS–DRG.

The Spiration® IBV Valve System device, a bronchial valve, was approved for new technology add-on payments in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43819 through 43823) with a maximum payment rate of $3,437.50. In the FY 2012 IPPS/LTCH PPS final rule, the new technology add-on payments were discontinued for FY 2012 (76 FR 51575 through 51576). The bronchial valve device is used to place, via bronchoscopy, small, one-way valves into selected small airways in the lung in order to limit airflow into selected portions of lung tissue that have prolonged air leaks following surgery while still allowing mucus, fluids, and air to exit, and thereby reducing the amount of air that enters the pleural space. The device is intended to control prolonged air leaks following three specific surgical procedures: lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). According to Spiration®, an air leak that is present on postoperative day 7 is considered ''prolonged'' unless present only during forced exhalation or cough. In order to help prevent valve migration, there are five anchors with tips that secure the valve to the airway. The implanted valves are intended to be removed no later than 6 weeks after implantation.

New technology add-on payments were limited to cases involving prolonged air leaks following lobectomy, segmentectomy, and LVRS in MS–DRGs 163, 164, and 165 in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43823). This limitation was based on the indications for use approved by the FDA in the FDA Humanitarian Device Exemption (HDE) approval process set forth in section 520(m) of the Federal Food, Drug & Cosmetic Act. A humanitarian use device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive HUD designation may be eligible for marketing approval, subject to certain restrictions, under an HDE application. To obtain marketing approval for an HUD, an HDE application must be submitted to the FDA. An HDE application is a premarket approval (PMA) application submitted to the FDA under 21 CFR 814.104 that seeks exemption from the PMA requirement under 21 CFR 814.20 demonstrating a reasonable assurance of effectiveness. A device that has received HUD designation may receive HDE approval if, among other things, the FDA determines that the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. In addition, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition (other than another device approved under an HDE application or a device under an approved Investigational Device Exemption), and that the device would not otherwise be available unless an HDE is granted. An approved HDE authorizes marketing of the HUD. However, an HUD generally may be used in facilities only after prior approval by an Institutional Review Board (IRB).

FDA's approval of the HDE application limited the use of the Spiration® IBV Valve System device to cases involving prolonged air leaks following lobectomy, segmentectomy, or LVRS.

The requested MS–DRG change would initiate the same payment for chronic obstructive pulmonary disease (COPD) cases with a bronchial valve inserted without a major chest procedure as for cases where both a major chest procedure and a bronchial valve insertion were performed. The following table shows the COPD cases that involved the insertion of a bronchial valve as well as data on cases assigned to MS–DRGs 163, 164, and 165.

MS–DRGs	Number of cases	Average length of stay	Average costs
COPD Cases			
MS–DRG 190—All cases	133,566	5.07	$7,815
MS–DRG 190—Cases with procedure code 33.71	0	0	0
MS–DRG 190—Cases with procedure code 33.73	2	14.0	47,034
MS–DRG 191—All cases	129,231	4.18	6,245
MS–DRG 191—Cases with procedure code 33.71	0	0	0
MS–DRG 191—Cases with procedure code 33.73	0	0	0
MS–DRG 192—All cases	93,507	3.32	4,776
MS–DRG 192—Cases with procedure code 33.71	0	0	0
MS–DRG 192—Cases with procedure code 33.73	0	0	0

MS–DRGs	Number of cases	Average length of stay	Average costs
Major Chest Procedures			
MS–DRG 163—All cases	11,287	13.33	32,728
MS–DRG 164—All cases	16,113	6.69	17,494
MS–DRG 165—All cases	9,280	3.94	12,209

There were only two COPD cases that had bronchial valves inserted in MS–DRGs 190, 191, and 192. While the charges were high, these cases were assigned to the highest severity level MS–DRG (MS–DRG 190 with MCC). Given the small number of cases, it is not possible to determine if the high average costs were due to the bronchial valve insertion or to other factors such as other secondary diagnoses. The average length of stay for these two cases was approximately 14 days compared to approximately 5.07 days for all other cases within MS–DRG 190. Because the additional 10 days cannot be clinically attributed to the bronchial valve insertion, our clinical advisors have determined that other factors must have impacted these two cases.

Cases in MS–DRGs 163, 164, and 165 include those cases with a major chest procedure and those cases with both a major chest procedure as well as a bronchial valve insertion as discussed above. Our clinical advisors do not support moving COPD cases that have only a bronchial valve insertion and no other major chest procedure from MS–DRGs 190, 191, and 192 to MS–DRGs 163, 164, and 165. They do not believe the bronchial valve procedures are clinically similar to other major chest procedures that require significantly more resources to perform. Our clinical advisors point out that the limited circumstances where this procedure would be used led the sponsor to seek HDE approval from the FDA rather than a standard PMA. The indications for use approved by the FDA are still limited to post-surgery. Our clinical advisors recommended that we not modify the MS–DRG logic so that COPD cases with bronchial valve insertions would be assigned to MS–DRGs 163, 164, and 165.

Given the limited number of cases for this procedure and the advice from our clinical advisors, we are not proposing any MS–DRG changes for bronchial valve(s) insertion for FY 2014. We also are not proposing to change the MS–DRG assignment for procedures involving bronchial valve(s) insertion (procedure codes 33.71 and 33.73) within MS–DRGs 190, 191, and 192.

We are inviting public comment on this issue.

b. Pulmonary Thromboendarterectomy (PTE) with Full Circulatory Arrest

We received a request from a university medical center to create a new MS–DRG or to reassign cases reporting a unique approach to pulmonary thromboendarterectomy (PTE) surgery performed with full cardiac arrest and hypothermia. The requestor asked that we move cases from MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively). Currently, MS–DRGs 163, 164, and 165 are grouped within MDC 4 (Diseases and Disorders of the Respiratory System) while MS–DRGs 228, 229, and 230 are grouped within MDC 5 (Diseases and Disorders of the Circulatory System).

The requestor identified two conditions for which a pulmonary endarterectomy procedure is typically performed. These conditions are identified by ICD–9–CM diagnosis codes 415.19 (Other pulmonary embolism and infarction) and 416.2 (Chronic pulmonary embolism). However, the requestor noted that diagnosis code 415.19 is usually associated with traditional PTE for acute pulmonary embolism while diagnosis code 416.2 is associated with the medical center's unique approach to PTE performed with full cardiac arrest and hypothermia.

Currently, there is not a specific ICD–9–CM procedure code to accurately describe PTE surgery performed with full cardiac arrest and hypothermia. Rather, a subset of existing ICD–9–CM procedure codes may be used to identify the various components involved in this unique approach to PTE surgery; for example, ICD–9–CM procedure codes 38.15 (Endarterectomy, other thoracic vessels); 39.61 (Extracorporeal circulation auxiliary to open heart surgery); 39.62 (Hypothermia (systemic) incidental to open heart surgery); and 39.63 (Cardioplegia). However, it is not clear if the requestor reports any of these codes or a combination of these codes to identify its unique approach to the procedure.

According to the requestor, its approach to PTE surgery is significantly different from traditional pulmonary endarterectomy procedures in terms of complexity, resource use, and the population for which the procedure is performed. The requestor noted that the surgery is ''conducted under profound hypothermia and circulatory arrest which involves placing the patient on cardiopulmonary bypass and cooling the body to 20 degrees centigrade or lower.'' In addition, the requestor explained that ''during this period of cooling and cardiac arrest, the heart is arrested and all of the patient's blood is removed from the body.'' Following this, circulation is stopped completely allowing for ''optimal and extensive dissection of the pulmonary arteries and identification of an endarterectomy plane which can be delicately incised into the deepest pulmonary vasculature.'' The requestor further noted that ''due to the complexity of the surgical technique, a very high degree of skill is required and the procedure is currently only performed by a handful of surgeons world-wide.'' Lastly, the requestor stated the average operating time for a traditional PTE is approximately 3 to 4 hours compared to the university medical center's approach to PTE, which averages approximately 10 to 12 hours.

We analyzed claims data from the FY 2012 MedPAR file for cases reporting a principal diagnosis code of 415.19 or a principal diagnosis code of 416.2 along with procedure codes 38.15, 39.61, 39.62, and 39.63. As displayed in the table below, there were a total of 11,287 cases in MS–DRG 163 with an average length of stay of approximately 13.33 days and average costs of approximately $32,728. Using the combination of diagnosis and procedure codes as described above, the total number of cases found in MS–DRG 163 was 12, with average costs ranging from approximately $46, 959 to $53,048 and an average length of stay ranging from approximately 13.50 days to 16.20 days. We acknowledge that the average length of stay and average costs for these cases are somewhat higher in comparison to

the average lengths of stay and average costs of all the other cases in MS–DRG 163. However, the volume of cases was very low. The data reflect similar results for MS–DRG 164. Only 4 cases were identified in the analysis, with average costs ranging from approximately $21,669 to $37,447 and average lengths of stay ranging from approximately 7 days to 10 days.

In total, there were only 16 cases reflected in the data using the combination of diagnosis codes and proxy procedure codes. We believe there may be other factors contributing to the increased lengths of stay and costs. (We note that, there were no cases found for a principal diagnosis code of 415.19 with procedure code 38.15 only. There also were no cases found in MS–DRG 165 using the combination of diagnosis and procedure codes.)

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 163—All cases	11,287	13.33	$32,728
MS–DRG 163—Cases with principal diagnosis code 415.19 with procedure code 38.15 and 39.61 or 39.62 or 39.63	4	13.50	46,959
MS–DRG 163—Cases with principal diagnosis code 416.2 with procedure code 38.15 only	3	14.33	53,048
MS–DRG 163—Cases with principal diagnosis code 416.2 with procedure code 38.15 and 39.61 or 39.62 or 39.63	5	16.20	50,393
MS–DRG 164—All cases	16,113	6.69	17,494
MS–DRG 164—Cases with principal diagnosis code 415.19 with procedure code 38.15 with 39.61 or 39.62 or 39.63	2	10.00	37,447
MS–DRG 164—Cases with principal diagnosis code 416.2 with procedure code 38.15 only	0	0	0
MS–DRG 164—Cases with principal diagnosis code 416.2 with procedure code 38.15 and 39.61 or 39.62 or 39.63	2	7.00	21,669

As stated in previous rulemaking discussion, the MS–DRG classification system on which the IPPS is based comprises a system of averages. As such, it is understood that, in any particular MS–DRG, it is not unusual for a small number of cases to demonstrate higher than average costs, nor is it unusual for a small number of cases to demonstrate lower than average costs. Upon review of the MedPAR data, our clinical advisors agree that the current MS–DRG assignment for this unique procedure is appropriate.

We also analyzed claims data from the FY 2012 MedPAR file for MS–DRGs 228, 229, and 230 as illustrated below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 228—Other cardiothoracic procedures with MCC	1,643	13.26	$46,758
MS–DRG 229—Other cardiothoracic procedures with CC	1,841	7.77	30,432
MS–DRG 230—Other cardiothoracic procedures without CC/MCC	506	5.08	25,068

ICD–9–CM procedure code 38.15 is designated as an operating room (OR) procedure code and currently groups to MS–DRGs 163, 164, and 165 in MDC 4 when either diagnosis code 415.19 or 416.2 are reported as the principal diagnosis. As diagnosis codes can only be assigned to one MDC within the GROUPER logic, it is not possible for a patient to have diagnosis code 415.19 or diagnosis code 416.2 reported along with procedure code 38.15 and grouped to MDC 5, which is where MS–DRGs 228, 229, and 230 are assigned.

Therefore, another aspect of this MS–DRG request involved the evaluation of moving ICD–9–CM diagnosis code 416.2 from MDC 4 to MDC 5. Our clinical advisors do not support moving diagnosis code 416.2 from MDC 4 to MDC 5 in order to accommodate this rare procedure performed by only a small number of physicians worldwide. They pointed out that a basic change such as moving diagnosis code 416.2 from MDC 4 to MDC 5 would impact a large number of patients who do not undergo this procedure. It also would disrupt trend data from over 30 years of DRG and MS–DRG reporting. Given the very small number of potential cases, and the advice of our clinical advisors, we do not believe a MS–DRG modification is warranted at this time.

Therefore, we are not proposing to create a new MS–DRG or to reassign cases reporting this university medical center's approach to pulmonary thromboendarterectomy. We are inviting public comments on this issue.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Discharge/Transfer to Designated Disaster Alternative Care Site

We are proposing to add new patient discharge status code 69 (Discharged/transferred to a designated disaster alternative care site) to the MS–DRG GROUPER logic for MS–DRGs 280 (Acute Myocardial Infarction Discharged Alive with MCC), 281 (Acute Myocardial Infarction Discharged Alive with CC), and 282 (Acute Myocardial Infarction Discharged Alive without CC/MCC) to identify patients who are discharged or transferred to an alternative site that will provide basic patient care during a disaster response. As discussed in section II.G.7. of the preamble of this proposed rule, this new discharge status code is also being added to the Medicare Code Editor (MCE) software. We are inviting public comments on this proposal.

b. Discharges/Transfers With a Planned Acute Care Hospital Inpatient Readmission

We also are proposing to add 15 new discharge status codes to the MS–DRG GROUPER logic for MS–DRGs 280, 281, and 282 that will identify patients who are discharged with a planned acute care hospital inpatient readmission. As discussed in section II.G.7. of the preamble of this proposed rule, these new discharge status codes are being proposed for addition to the MCE as well.

Shown in the table below are the current discharge status codes that are

assigned to the GROUPER logic for MS–DRGs 280, 281, and 282, along with the proposed new discharge status codes and their titles.

Current code	New code	Title
01	81	Discharged to home or self care with a planned acute care hospital inpatient readmission.
02	82	Discharged/transferred to a short term general hospital for inpatient care with a planned acute care hospital inpatient readmission.
03	83	Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification with a planned acute care hospital inpatient readmission.
04	84	Discharged/transferred to a facility that provides custodial or supportive care with a planned acute care hospital inpatient readmission.
05	85	Discharged/transferred to a designated cancer center or children's hospital with a planned acute care hospital inpatient readmission.
06	86	Discharged/transferred to home under care of organized home health service organization with a planned acute care hospital inpatient readmission.
21	87	Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission.
43	88	Discharged/transferred to a federal health care facility with a planned acute care hospital inpatient readmission.
61	89	Discharged/transferred to a hospital-based Medicare approved swing bed with a planned acute care hospital inpatient readmission.
62	90	Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned acute care hospital inpatient readmission.
63	91	Discharged/transferred to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission.
64	92	Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare with a planned acute care hospital inpatient readmission.
65	93	Discharged/transferred to a psychiatric distinct part unit of a hospital with a planned acute care hospital inpatient readmission.
66	94	Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission.
70	95	Discharged/transferred to another type of health care institution not defined elsewhere in this code list with a planned acute care hospital inpatient readmission.

We are inviting public comments on our proposal to add the above listed new discharge status codes to the GROUPER logic for MS–DRGs 280, 281, and 282.

5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Reverse Shoulder Procedures

We received a request to change the MS–DRG assignment for reverse shoulder replacement procedures which is captured with procedure code 81.88 (Reverse total shoulder replacement). The requestor did not suggest a specific new MS–DRG assignment, but requested that reverse shoulder replacement procedures be reassigned from MS–DRGs 483 and 484 (Major Joint/Limb Reattachment Procedure of, Upper Extremities with CC/MCC and without CC/MCC, respectively) or that we create a new MS–DRG for reverse shoulder replacement procedures.

Biomechanically, the reverse shoulder devices move the center of rotation of the arm laterally and change the direction of the pull of the deltoid muscle, allowing the deltoid muscle to elevate the arm without functioning rotator cuff tendons. The requestor stated that the use of traditional total shoulder devices in patients with a nonfunctioning rotator cuff frequently leads to long-term complications and unsatisfactory functional results. Patients with damaged rotator cuffs or rotator cuff syndrome have poor outcomes with traditional shoulder replacement devices. The reverse shoulder replacement procedure was created to address the clinical needs for patients who would have poor outcomes with a traditional shoulder replacement. The requestor stated that reverse shoulder replacement devices were designed to provide a superior functionality and outcomes for patients with damaged rotator cuffs.

The requestor stated that the reverse shoulder replacement procedure is technically more complex and requires a higher level of expertise than traditional shoulder procedures and involves several issues that make the surgery more complex. Patients who have had prior rotator cuff surgery have anchors and scar tissue that must be surgically addressed. Often, there also are severe deformities that must be addressed in order to establish stability.

The requestor acknowledged that the reverse shoulder replacement procedure is an upper extremity procedure like other procedures assigned to MS–DRGs 483 and 484. These MS–DRGs include the longstanding total shoulder replacement procedures as well as partial shoulder replacements. While the procedure is similar to other procedures in MS–DRGs 483 and 484, the requestor stated there are significant differences between the technical complexity and indications for usage from the other procedures. The requestor stated there are significant differences in resource usage and clinical coherence between longstanding approaches to shoulder replacement and other procedures assigned to MS–DRGs 483 and 484 and the reverse shoulder replacement procedure. The requestor stated not only was the resource consumption significantly higher, the individual supply costs for reserve shoulder replacement procedures were higher than the costs of other procedures assigned to MS–DRGs 483 and 484.

MS–DRGs 483 and 484 contain the following procedures:

- 81.73 (Total wrist replacement)
- 81.80 (Other total shoulder replacement)
- 81.81 (Partial shoulder replacement)
- 81.84 (Total elbow replacement)
- 81.88 (Reverse total shoulder replacement)
- 84.23 (Forearm, wrist, or hand reattachment)
- 84.24 (Upper arm reattachment).

As can be seen from this list, MS–DRGs 483 and 484 contain total and partial shoulder replacements, as well as replacement and attachment procedures on the wrist and upper arm. Both the newer shoulder replacement techniques as well as the longstanding

shoulder replacement techniques are included in these MS–DRGs.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 483—All cases	13,113	3.33	$17,039
MS–DRG 483—Cases with procedure code 81.88	5,690	3.30	19,023
MS–DRG 484—All cases	21,073	2.01	14,448
MS–DRG 484—Cases with procedure code 81.88	7,505	2.08	16,890

As the above table illustrates, the average costs for reverse total shoulder replacement are approximately $2,000 higher than the average costs for all other procedures within MS–DRGs 483 and 484 and have similar average lengths of stays. While the average costs were higher, each MS–DRG has some cases that are higher and some cases that are lower than the average costs for the entire MS–DRG. We believe the average costs for the reverse shoulder replacement procedures are not inappropriately high compared to other procedures grouped within MS–DRGs 483 and 484. Therefore, the claims data do not support reassigning these cases or creating a new MS–DRG.

Our clinical advisors reviewed this issue and determined that the cases are appropriately assigned to MS–DRGs 483 and 484. As stated earlier, MS–DRGs 483 and 484 contain other types of shoulder replacements. Our clinical advisors believe it is appropriate to have all total shoulder replacement procedures within the same set of MS–DRGs. They do not believe it is appropriate to reassign those that use a different technique to accomplish the same goal, a total shoulder replacement. Therefore, our clinical advisors determined that this is an appropriate assignment for reverse shoulder replacement procedures from a clinical perspective. They also do not believe it is appropriate to move these cases to any other surgical, orthopedic MS–DRGs because of differences in the clinical makeup of the other surgical orthopedic MS–DRGs. Our clinical advisors recommended not creating a new MS–DRG for reverse shoulder replacement procedures because they believe the procedures are appropriately assigned to MS–DRGs 483 and 484. Therefore, based on claims data and clinical analysis, we are not proposing to reassign these cases to any other MS–DRGs or to create a new MS–DRG.

Based on the claims data and our clinical analysis, we are not proposing to reassign cases reporting procedure code 81.88 from their current assignment to MS–DRGs 483 and 484 or to create a new MS–DRG. We are inviting public comments on this issue.

b. Total Ankle Replacement Procedures

In response to the FY 2013 IPPS/LTCH PPS proposed rule, we received a request to develop a new MS–DRG for total ankle replacements, which we considered to be outside the scope of that proposed rule (77 FR 53325). We are addressing this request as part of this FY 2014 IPPS/LTCH PPS proposed rule. The cases are captured by procedure code 81.56 (Total ankle replacement) and are assigned to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with MCC and without MCC, respectively).

The commenter stated that total ankle procedures are much more clinically complex than total hip or total knee replacement procedures, which have their own distinct MS–DRGs. The commenter also stated that total ankle replacement is surgery that involves the replacement of the damaged parts of the three bones that make up the ankle joint, as compared to two bones in most other total joint procedures such as hip or knee replacement. The commenter stated that average costs of total ankle replacements are higher than those for total knee and hip replacements. Therefore, a new MS–DRG should be created for total ankle replacements. As an alternative, the commenter suggested that these cases be reassigned to MS–DRG 469 even if the cases do not have an MCC as a secondary diagnosis.

MS–DRGs 469 and 470 include a variety of procedures of the lower extremities including the procedures listed below. This group of lower extremity joint replacement and reattachment procedures was developed because they were considered to be clinically cohesive and to have similar resource consumptions.

- 00.85 (Resurfacing hip, total, acetabulum and femoral head)
- 00.86 (Resurfacing hip, partial, femoral head)
- 00.87 (Resurfacing hip, partial, acetabulum)
- 81.51 (Total hip replacement)
- 81.52 (Partial hip replacement)
- 81.54 (Total knee replacement)
- 81.56 (Total ankle replacement)
- 84.26 (Foot reattachment)
- 84.27 (Lower leg or ankle reattachment)
- 84.28 (Thigh reattachment)

As the table below shows, there were 1,275 cases reporting total ankle replacements with 21 cases in MS–DRG 469 and 1,254 cases in MS–DRG 470. The 1,254 cases in MS–DRG 470 have higher costs than other cases in MS–DRG 470 (approximately $17,242 compared to approximately $13,984). The 21 cases in MS–DRG 469 had average costs of approximately $23,360 compared to approximately $21,186 in average costs for all cases within MS–DRG 469. While these procedures are higher in average costs than other procedures within the MS–DRGs, we point out that cases are grouped together based on similar clinical and resource criteria. Some cases will have average costs higher than the overall average costs for the MS–DRG, while other cases will have lower average costs. Total ankle replacements represent 0.3 percent of the total number of cases within MS–DRGs 469 and 470.

MS–DRGs	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,618	7.33	$21,186
MS–DRG 469—Cases with procedure code 81.56	21	6.81	23,360
MS–DRG 470—All cases	390,518	3.37	13,984
MS–DRG 470—Cases with procedure code 81.56	1,254	2.19	17,242

MS–DRGs	Number of cases	Average length of stay	Average costs
Total—All cases			416,136
Total—Cases with procedure code 81.56			1,275

Our clinical advisors reviewed this issue and determined that the total ankle replacements are appropriately classified within MS–DRGs 469 and 470. They do not support the commenter's contention that these cases are significantly more complex than knee and hip replacements. They believe that total ankle replacements are clinically consistent with other types of lower extremity joint replacements within MS–DRGs 469 and 470. Our clinical advisors do not support creating a new MS–DRG for total ankle replacements. After considering the results of examination of the claims data, the recommendations from our clinical advisors, and the small number of total ankle replacements, we are not proposing to create a new MS–DRG at this time.

We also examined the request to move all total ankle replacements to the highest severity level, MS–DRG 469, even when no secondary diagnosis on the MCC list was reported. Moving all total ankle replacements to MS–DRG 469 would lead to overpayments of approximately $3,944 per case because the average costs of total ankle replacements in MS–DRG 470 was approximately $17,242, while the average costs of all cases in MS–DRG 469 was approximately $21,186. After considering the claims data as well as the input from our clinical advisors, we are not proposing that all total ankle procedures be assigned to MS–DRG 469 even when the case does not have an MCC reported as a secondary diagnosis. We believe the current MS–DRGs are appropriate for total ankle replacements.

We are not proposing to create a new total ankle replacement MS–DRG or to reassign all total ankle replacements to MS–DRG 469. We are proposing to maintain the current MS–DRG assignments for total ankle replacements. We are inviting public comment on our proposal.

6. MDC 15 (Newborns and Neonates With Conditions Originating in the Neonatal Period)

a. Persons Encountering Health Services for Specific Procedures, Not Carried Out

We received a request to evaluate the MS–DRG assignment of ICD–9–CM diagnosis codes V64.00 through V64.04, and V64.06 through V64.43 in MS–DRG 794 (Neonate with Other Significant Problems) under MDC 15. The requestor noted that the assignment of diagnosis code V64.05 (Vaccination not carried out because of caregiver refusal) was addressed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50111 through 50112). We removed diagnosis code V64.05 from MS–DRG 794 and added it to the ''only secondary diagnosis'' list for MS–DRG 795 (Normal Newborn). The requestor asked that we consider the reassignment of these diagnosis codes from MS–DRG 794 to MS–DRG 795. The codes under existing MS–DRG 794 include:

- V64.00 (Vaccination not carried out, unspecified reason)
- V64.01 (Vaccination not carried out because of acute illness)
- V64.02 (Vaccination not carried out because of chronic illness or condition)
- V64.03 (Vaccination not carried out because of immune compromised state)
- V64.04 (Vaccination not carried out because of allergy to vaccine or component)
- V64.06 (Vaccination not carried out because of patient refusal)
- V64.07 (Vaccination not carried out for religious reasons)
- V64.08 (Vaccination not carried out because patient had disease being vaccinated against)
- V64.09 (Vaccination not carried out for other reason)
- V64.1 (Surgical or other procedure not carried out because of contraindication)
- V64.2 (Surgical or other procedure not carried out because of patient's decision)
- V64.3 (Procedure not carried out for other reasons)
- V64.41 (Laparoscopic surgical procedure converted to open procedure)
- V64.42 (Thoracoscopic surgical procedure converted to open procedure)
- V64.43 (Arthroscopic surgical procedure converted to open procedure).

In a newborn case with one of these diagnosis codes reported as a secondary diagnosis, the case would be assigned to MS–DRG 794. The commenter believed that these diagnosis codes, when reported as a secondary diagnosis for a newborn case, should be assigned to MS–DRG 795 instead of MS–DRG 794.

Our clinical advisors reviewed this request and concur with the commenter that diagnosis codes V64.00 through V64.04, and V64.06 through V64.3 should not continue to be assigned to MS–DRG 794, as there is no clinically usable information reported in those codes identifying significant problems. However, our clinical advisors recommend that diagnosis codes V64.41, V64.42, and V64.43, which identify that a surgical procedure converted to an open procedure, continue to be assigned to MS–DRG 794. These diagnosis codes may indicate a more significant encounter that required a surgical intervention.

Therefore, for FY 2014, we are proposing to reassign diagnosis codes V64.00 through V64.04, and V64.06 through V64.3 from MS–DRG 794 to MS–DRG 795. Diagnosis codes V64.00 through V64.04, and V64.06 through V64.3 would be added to the ''only secondary diagnosis'' list for MS–DRG 795. Diagnosis codes V64.41, V64.42, and V64.43 would continue to be assigned to MS–DRG 794. We are inviting public comments on this proposal.

b. Discharges/Transfers of Neonates With a Planned Acute Care Hospital Inpatient Readmission

We are proposing to add the patient discharge status codes shown in the table below to the MS–DRG GROUPER logic for MS–DRG 789 (Neonates, Died or Transferred to Another Acute Care Facility) to identify neonates that are transferred to a designated facility with a planned acute care hospital inpatient readmission.

New code	Title
82	Discharged/transferred to a short term general hospital for inpatient care with a planned acute care hospital inpatient readmission.

New code	Title
85	Discharged/transferred to a designated cancer center or children's hospital with a planned acute care hospital inpatient readmission.
94	Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission.

Currently, the GROUPER logic for MS–DRG 789 contains discharge status codes 02 (Discharged/transferred to a short term general hospital for inpatient care), 05 (Discharged/transferred to a designated cancer center or children's hospital), and 66 (Discharged/transferred to a critical access hospital (CAH)).

As discussed in section II.G.7. of the preamble of this proposed rule, these new discharge status codes are also being proposed for addition to the Medicare Code Editor (MCE). We are inviting public comments on our proposal.

7. Proposed 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.

a. Age Conflict Edit

We received a request to review three ICD–9–CM diagnosis codes currently listed under the age conflict edit within the MCE. The age conflict edit detects inconsistencies between a patient's age and any diagnosis on the patient's record. Specifically, the requestor recommended that CMS consider the removal of diagnosis codes 751.1 (Atresia and stenosis of small intestine), 751.2 (Atresia and stenosis of large intestine, rectum, and anal canal), and 751.61 (Biliary atresia) from the pediatric age conflict edit. Generally, diagnoses included in the list for the pediatric age conflict edit are applicable for ages 0 through 17.

The requestor noted that diagnosis code 751.1 was removed from the Integrated Outpatient Code Editor (IOCE) effective January 1, 2006. Our clinical advisors agree that patients described with any one of the above listed codes, although congenital anomalies, may require a revision procedure in adulthood. Therefore, we believe that the removal of these codes appears appropriate and also would be consistent with the IOCE.

We are inviting public comments on our proposal to remove diagnosis codes 751.1, 751.2, and 751.61 from the pediatric age conflict edit effective October 1, 2013.

b. Discharge Status Code Updates

To reflect changes in the UB–04 code set maintained by the National Uniform Billing Committee (NUBC), we are proposing to add the following new discharge status codes to the CMS GROUPER and the MCE logic effective October 1, 2013.

One of the new discharge status codes corresponds to an alternative care site. This alternative care site discharge status code is intended to identify patients being discharged or transferred to an alternative site that will provide basic patient care during a disaster response. The new discharge status code is 69 (Discharged/transferred to a designated disaster alternative care site).

In addition, 15 new discharge status codes correspond with identifying planned acute care hospital inpatient readmissions. Shown below are the existing ''base'' discharge status codes and the new codes that will better identify patients who are discharged with a planned readmission.

Base code	New code	Title
01	81	Discharged to home or self care with a planned acute care hospital inpatient readmission.
02	82	Discharged/transferred to a short term general hospital for inpatient care.
03	83	Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification with a planned acute care hospital inpatient readmission.
04	84	Discharged/transferred to a facility that provides custodial or supportive care with a planned acute care hospital inpatient readmission.
05	85	Discharged/transferred to a designated cancer center or children's hospital with a planned acute care hospital inpatient readmission.
06	86	Discharged/transferred to home under care of organized home health service organization with planned acute care hospital inpatient readmission.
21	87	Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission.
43	88	Discharged/transferred to federal health care facility with a planned acute care hospital inpatient readmission.
61	89	Discharged/transferred to a hospital-based Medicare approved swing bed with a planned acute care hospital inpatient readmission.
62	90	Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned acute care hospital inpatient readmission.
63	91	Discharged/transferred to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission.
64	92	Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare with a planned acute care hospital inpatient readmission.
65	93	Discharged/transferred to a psychiatric distinct part unit of a hospital with a planned acute care hospital inpatient readmission.
66	94	Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission.
70	95	Discharged/transferred to another type of health care institution not defined elsewhere in this code list with a planned acute care hospital inpatient readmission.

We are inviting public comments on our proposal to add the above listed new discharge status codes to the GROUPER and the MCE logic effective October 1, 2013 (FY 2014).

8. 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 2014, 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.

In this proposed rule, we are proposing limited changes to the MS–DRG classifications for FY 2014, as discussed in sections II.G.2. and 5. of this preamble. In our review of these proposed changes, we did not identify any needed changes to the surgical hierarchy. Therefore, in this proposed rule, we are not proposing any changes to the surgical hierarchy for Pre-MDCs and MDCs for FY 2014.

9. Complications or Comorbidity (CC) Exclusions List

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Proposed CC Exclusions List for FY 2014

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.[1]

(1) No Proposed Revisions Based on Changes to the ICD–9–CM Diagnosis Codes for FY 2014

For FY 2014, there were no changes made to the ICD–9–CM coding system effective October 1, 2013, due to the partial code freeze. (We refer readers to section II.G.10. of the preamble of this proposed rule for a discussion of the ICD–9–CM coding system.)

(2) Suggested Changes to the MS–DRG Diagnosis Codes for FY 2014

(A) Coronary Atherosclerosis Due to Calcified Coronary Lesion

We received a request that we consider changing the severity levels for the following ICD–9–CM diagnosis code: 414.4 (Coronary atherosclerosis due to calcified coronary lesion). The requestor suggested that we change the severity level for diagnosis code 414.4 from a non-CC to an MCC.

The following chart shows the analysis of the MedPAR claims data for FY 2012 for ICD–9–CM diagnosis code 414.4.

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
414.4	Coronary atherosclerosis due to calcified lesion.	Non-CC	1,390	1.58	2,174	2.31	2,001	3.11

We ran the above data as described in the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161). 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 chart above shows that the C1 finding is 1.58. 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 the condition is expected to consume resources more similar to an MCC than a CC or a non-CC.

The C2 finding was 2.31. 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 1.58 is above the 1.0 value for a non-CC, it does not support reclassification to an MCC. 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 2.31 also does not support reclassifying this diagnosis code to an MCC. We also considered reclassifying the severity level of diagnosis code 414.4 to a CC; however, the C1 finding of 1.58 also does not support reclassifying the severity level to a CC. Our clinical advisors reviewed the data and evaluated this condition. They recommended that we not change the severity level of diagnosis code 414.4 from a non-CC to an MCC or a CC. They do not believe that this diagnosis would increase the severity level of patients. They pointed out that a similar code, diagnosis code 414.2 (Chronic total occlusion of coronary artery), is a non-CC. Our clinical advisors believe that diagnosis code 414.4 represents patients who are less severe than diagnosis code 414.2. Considering the C1 and C2 ratings and the input from our clinical advisors, we are not proposing to reclassify diagnosis code 414.4 to an MCC; the diagnosis code would continue to be considered a non-CC.

Therefore, based on the data and clinical analysis, we are proposing to maintain diagnosis code 414.4 as a non-CC. We are inviting public comment on our proposal.

(B) Acute Cholecystitis Diagnosis Code

We received a comment recommending that we add diagnosis code 575.0 (Acute cholecystitis) to the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code 574.00 (Calculus of gallbladder with acute cholecystitis without mention of obstruction). We note that, there is an ''excludes note'' under diagnosis code 575.0 which excludes ''that with cholelithiasis (574.00)''. Therefore, diagnosis codes 575.0 and 574.00 should not be reported on the same claim. However, the commenter stated that there may be double reporting.

Our clinical advisors agree with the commenter that diagnosis codes 575.0 and 574.00 capture the same clinical context. Therefore, we are proposing to add diagnosis code 575.0 to the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code 574.00. We are

[1] 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); and the FY 2013 final rule (77 FR 53315). 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.

inviting public comments on our proposal.

(C) Chronic Total Occlusion (CTO) of Artery of the Extremities Diagnosis Code

We received a request to consider removing atherosclerosis and aneurysm codes from the CC Exclusion List for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities). For FY 2013, we changed the designation of diagnosis code 440.4 from a non-CC level to a CC level. The CC Exclusion List for diagnosis code 440.4 includes the following diagnosis codes:

Diagnosis code	Code description
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.
440.30	Atherosclerosis of unspecified bypass graft of the extremities.
440.31	Atherosclerosis of autologous vein bypass graft of the extremities.
440.32	Atherosclerosis of nonautologous biological bypass graft of the extremities.
440.4	Chronic total occlusion of artery of the extremities.
441.00	Dissection of aorta, unspecified site.
441.01	Dissection of aorta, thoracic.
441.02	Dissection of aorta, abdominal.
441.03	Dissection of aorta, thoracoabdominal.
441.1	Thoracic aneurysm, ruptured.
441.2	Thoracic aneurysm without mention of rupture.
441.3	Abdominal aneurysm, ruptured.
441.4	Abdominal aneurysm without mention of rupture.
441.5	Aortic aneurysm of unspecified site, ruptured.
441.6	Thoracoabdominal aneurysm, ruptured.
441.7	Thoracoabdominal aneurysm, without mention of rupture.
441.9	Aortic aneurysm of unspecified site without mention of rupture.
442.0	Aneurysm of artery of upper extremity.
442.2	Aneurysm of iliac artery.
442.3	Aneurysm of artery of lower extremity.
442.9	Aneurysm of unspecified site.
443.22	Dissection of iliac artery.
443.29	Dissection of other artery.
443.81	Peripheral angiopathy in diseases classified elsewhere.
443.82	Erythromelalgia.
443.89	Other specified peripheral vascular diseases.
443.9	Peripheral vascular disease, unspecified.
444.01	Saddle embolus of abdominal aorta.
444.09	Other arterial embolism and thrombosis of abdominal aorta.
444.1	Embolism and thrombosis of thoracic aorta.
444.21	Arterial embolism and thrombosis of upper extremity.
444.22	Arterial embolism and thrombosis of lower extremity.
444.81	Embolism and thrombosis of iliac artery.
444.89	Embolism and thrombosis of other specified artery.
444.9	Embolism and thrombosis of unspecified artery.
445.01	Atheroembolism of upper extremity.
445.02	Atheroembolism of lower extremity.
445.81	Atheroembolism of kidney.
445.89	Atheroembolism of other site.
447.0	Arteriovenous fistula, acquired.
447.1	Stricture of artery.
447.2	Rupture of artery.
447.5	Necrosis of artery.
447.6	Arteritis, unspecified.
447.70	Aortic ectasia, unspecified site.
447.71	Thoracic aortic ectasia.
447.72	Abdominal aortic ectasia.
447.73	Thoracoabdominal aortic ectasia.
449	Septic arterial embolism.

Diagnosis code 440.4 is a CC except if one of the diagnosis codes listed above is reported as a principal diagnosis. If one of the diagnosis codes listed above is reported on a claim as a principal diagnosis and code 440.4 is reported as a secondary diagnosis, code 440.4 would not be counted as a CC. The commenter requested that we remove atherosclerosis codes 440.20 through 440.32, 443.22, 443.29, 443.81 through 443.9, and aneurysm codes 441.00 through 441.03, 441.1 through 441.7, 441.9, 442.0, 442.2, 442.3, and 442.9 from the CC Exclusion List for diagnosis code 440.4.

According to the commenter, aneurysm diagnoses are not closely related clinically to peripheral CTOs. Aneurysm physiology, clinical symptomology, and patient risk profile

are fundamentally different than CTOs. Aneurysms result from the weakening of an artery wall and manifest in an out-pouched pocket of the lumen. Conversely, patients with CTOs present with extended segments of diseased and narrowed vessels and in most cases, complex lesions containing fibro-calcified plaques. The commenter stated that CTOs represent a high severity complication, which is not closely related to basic atherosclerosis.

Our clinical advisors agree with the commenter that the aneurysm and most of the atherosclerosis codes should be removed from the CC Exclusion List for diagnosis code 440.4. A case with a principal diagnosis of aneurysm with CTO adds substantial complexity and does not necessarily have the same immediate cause. A case with a principal diagnosis of atherosclerosis with CTO reported represents a more severe form of the disease and, therefore, is more complex. Our clinical advisors do not agree with the commenter that diagnosis codes 443.81 through 443.9 (Other and unspecified peripheral vascular diseases) should be removed from the CC Exclusion List. These cases are more likely related to CTO and meet one of the principles for exclusion that we previously outlined above.

Therefore, for FY 2014, we are proposing to remove the following diagnosis codes from the CC Exclusion List for diagnosis code 440.4: atherosclerosis codes 440.20 through 440.32, 443.22, and 443.29, and aneurysm codes 441.00 through 441.03, 441.1 through 441.7, 441.9, 442.0, 442.2, 442.3, and 442.9. Diagnosis codes 443.81 through 443.9 would remain on the CC Exclusion List for diagnosis code 440.4. We are inviting public comments on this proposal.

For FY 2014, we are proposing changes to Table 6G (Additions to the CC Exclusion List) and Table 6H (Deletions from the CC Exclusion List). As we discussed earlier, we are not proposing changes to the severity level for diagnosis code 414.4. These tables, which contain codes that are effective for discharges occurring on or after October 1, 2013, are not being published in the Addendum to this proposed rule because of the length of the two tables. Instead, we are making them available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Each of these principal diagnosis codes for which there is a CC exclusion is shown in Tables 6G and 6H with an asterisk, and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Beginning with discharges on or after October 1 of each fiscal year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

There are no new, revised, or deleted diagnosis codes for FY 2014. Therefore, there are no Tables 6A, 6C, and 6E published for FY 2014.

There are no proposed additions or deletions to the MS–DRG MCC List for FY 2014. There also are no proposed additions or deletions to the MS–DRG CC List for FY 2014. Therefore, there are no Tables 6I.1 through 6I.2 and 6J.1 through 6J.2 published for FY 2014.

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current MS–DRG Definitions Manual, Version 30.0, is available on a CD for $225.00. Version 31.0 of this manual, which will include the final FY 2014 MS–DRG changes, will be available on a CD for $225.00. These manuals 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: *http://www.3MHIS.com*. Please specify the revision or revisions requested.

10. 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)
- 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.[2]

[2] 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

Our review of MedPAR claims data showed that there were no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2014, we are not proposing to change the procedures assigned among these MS–DRGs.

a. Moving Procedure Codes from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As noted above, there were no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2014, we are not proposing 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.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

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 were 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 2014, we are not proposing to move any procedure codes among these MS–DRGs.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs as described above in sections II.G.1. through 6. of this preamble, we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2014.

11. Proposed Changes to the ICD–9–CM Coding System, Including Discussion of the Replacement of the ICD–9–CM Coding System With the ICD–10–CM and ICD–10–PCS Systems in FY 2014

a. ICD–9–CM Coding System

The ICD–9–CM is a coding system currently used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, cochaired 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 Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM 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 valid ICD–9–CM diagnosis and procedure codes can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the 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 2014 at a public meeting held on September 19, 2012, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 16, 2012. There were no changes to the ICD–9–CM coding system for FY 2014. There were no new, revised or deleted diagnosis or procedure codes for FY 2014.

The Committee held its 2013 meeting on March 5, 2013. Any new codes for which there was consensus of public support and for which complete tabular and indexing changes will be made by May 2013 will be included in the

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, and 2013, 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), and in the FY 2013 final rule (77 FR 53321).

October 1, 2013 update to ICD–9–CM. Any code revisions that were discussed at the March 5, 2013 Committee meeting but that could not be finalized in time to include them in the tables listed in section VI. of the Addendum to this proposed rule will be included in Table 6B, which is listed in section VI. of the Addendum to the final rule and available via the Internet on the CMS Web site, and will be marked with an asterisk (*).

For FY 2014, there were no changes to the ICD–9–CM coding system due to the partial code freeze or for new technology. Therefore, there are no new, revised, or deleted diagnosis codes and no new, revised, or deleted procedure codes that are usually announced in Tables 6A (New Diagnosis Codes), 6B (New Procedure Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, there are no Tables 6A through 6F published as part of this proposed rule for FY 2014. We note that, there may be ICD–9–CM coding changes finalized after this proposed rule based on public comments that we receive after the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. If there are changes, we will include these changes in the final rule.

Copies of the minutes of the procedure codes discussions at the Committee's September 19, 2012 meeting and March 5, 2013 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp*. The minutes of the diagnosis codes discussions at the September 19, 2012 meeting and March 5, 2013 meeting are found at: *http://www.cdc.gov/nchs/icd.htm*. These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–9–CM 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 E. Brooks, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, 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–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 ICD–9–CM Coordination and Maintenance 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 changes to ICD–9–CM, 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–9–CM Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no

requests approved for an expedited April l, 2013 implementation of an ICD–9–CM code at the September 19, 2012 Committee meeting. Therefore, there were no new ICD–9–CM codes implemented on April 1, 2013.

Current addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. Information on ICD–9–CM diagnosis codes, along with the Official ICD–9–CM Coding Guidelines, can be found on the Web site at: *http://www.cdc.gov/nchs/icd9.htm*. Information on new, revised, and deleted ICD–9–CM codes is also provided to the AHA for publication in the *Coding Clinic for ICD–9–CM.* AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–9–CM coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

These same means of disseminating information on new, revised, and deleted ICD–9–CM codes will be used to notify providers, publishers, software vendors, contractors, and others of any changes to the ICD–9–CM codes that are implemented in April. The code titles are adopted as part of the 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. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. For codes that are implemented in April, we will assign the new procedure code to the same MS–DRG in which its predecessor code was assigned so there will be no MS–DRG impact as far as MS–DRG assignment. Any midyear coding updates will be available through the Web sites indicated above and through the *Coding Clinic for ICD–9–CM.* Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these Web sites 5 months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates.

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD–10) coding system applicable to hospital inpatient services was to be implemented on 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 (74 FR 3328 through 3362, January 16, 2009). However, the Secretary of Health and Human Services issued a final rule that delays, from October 1, 2013, to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD–10). The final rule, 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*.

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 ICM–10–PCS Guidelines for Coding and Reporting. In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362), 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 will 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, as the system would no longer be a HIPAA standard and, therefore, no longer be used for reporting.
- On October 1, 2015, one year after the implementation of ICD–10, regular updates to ICD–10 will begin.

The 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 on or after October 1, 2015, 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–9–CM Coordination and Maintenance Committee Web site at: *http://www.cms.hhs.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, are posted on the Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html*.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

CMS is currently processing all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Prior to January 1,

2011, hospitals could submit up to 25 diagnoses and 25 procedures. However, CMS' system limitations allowed for the processing of only the first 9 diagnosis codes and 6 procedure codes. We discussed this change in processing claims in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25843), in a correction notice issued in the **Federal Register** on June 14, 2011 (76 FR 24633), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51553). As discussed in these prior rules, CMS undertook an expansion of our internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update. We recognize the value of the additional information provided by this coded data for multiple uses such as for payment, quality measures, outcome analysis, and other important uses. We will continue to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format.

d. ICD–10 MS–DRGs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received 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). As we stated earlier, the Secretary of Health and Human Services has delayed the compliance date of ICD–10 from October 1, 2013 to October 1, 2014 (77 FR 54664). 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 our current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–9–CM Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to go about 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 others to follow. All of this information can be found on the CMS Web site at: *http://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–9–CM Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

During FY 2011, we developed and posted Version 28.0 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRGs Version 28.0 also included the CC Exclusion List and the ICD–10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26.0. 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.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

We reviewed comments on the ICD–10 MS–DRGs Version 28.0 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 at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD10-MS-DRG-Conversion-Project.html*. 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–DRG Web page. We stated that we believed that, by providing the ICD–10 MS–DRG 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 29.0, based on the FY 2012 MS–DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29.0 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 28.0 to Version 29.0 to facilitate a review. The ICD–10 MS–DRGs Version 29.0 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 30.0 based on the FY 2013 MS–DRGs (Version 30.0) that we finalized in the FY 2013 IPPS/LTCH PPS final rule. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 30.0 on our 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 also prepared a document that describes changes made from Version 29.0 to Version 30.0 to facilitate a review. We produced mainframe and computer software for Version 30.0, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 30.0 computer software should facilitate additional review of the ICD–10 MS–DRGs conversion.

We provided information on a study conducted on the impact on 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 27.0 (FY 2010) and converted to the ICD–10 MS–DRGs Version 27.0. 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 2009 Medicare data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.0.

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 29.0. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. At this 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 updated paper is posted on CMS' Web site at: *http://cms.hhs.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://cms.hhs.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 30.0 software will provide additional information to the public who are evaluating the conversion of the MS–DRGs to ICD–10 MS–DRG.

We will continue to work with the public to explain how we are approaching the conversion of MS–DRGs to ICD–10 and will post drafts of updates as they are developed for public review. The final version of the ICD–10 MS–DRGs will be implemented at the same time as ICD–10 and will be subject to notice and comment rulemaking. In the meantime, we will provide extensive and detailed information on this activity through the ICD–9–CM Coordination and Maintenance Committee.

H. Recalibration of the Proposed FY 2014 MS–DRG Relative Weights

1. Data Sources for Developing the Proposed Relative Weights

In developing the proposed FY 2014 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 2012 MedPAR data used in this proposed rule include discharges occurring on October 1, 2011, through September 30, 2012, based on bills received by CMS through December 31, 2012, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2012 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,364,125 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2012 update of the FY 2012 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2014 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. The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2012 update of the FY 2011 HCRIS for calculating the proposed FY 2014 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.2. of the preamble of this proposed rule, we are proposing to calculate the relative weights based on 19 CCRs, instead of the 15 CCRs previously used. The methodology we used to calculate the proposed FY 2014 MS–DRG cost-based relative weights based on claims data in the FY 2012 MedPAR file and data from the FY 2011 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2014 MS–DRG classifications discussed in sections II.B. and II.G. of the preamble of this proposed 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 2011 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 92.7 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. For FY 2014, as explained in section II.E.2. of the preamble of this proposed rule, we are proposing to calculate the relative weights using 19 cost centers instead of the 15 cost centers previously used in calculating the FY 2013 relative weights. In calculating the FY 2014 relative weights, we also are proposing to continue to remove claims of providers with more than five blank cost centers from the dataset used to calculate the relative weights. (We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53326) for the edit threshold related to FY 2013 and prior fiscal years). In recent years, this trim

kept approximately 96 percent of IPPS providers in the MedPAR file upon which we base our relative weight calculations. (For examples of our FYs 2012 and 2013 relative weight calculations, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51558) and the FY 2013 IPPS/LTCH PPS final rule 77 FR 53326).) However, under the proposal presented in this proposed rule to add 4 cost centers to the relative weight calculations, this trim kept approximately 92.7 percent of the IPPS providers in the MedPAR file upon which we base our proposed FY 2014 relative weight calculations.

Although this trim is now removing a greater percentage of providers' claims from the relative weight calculations than were previously removed, we believe that it is appropriate to propose to continue to remove providers' claims that do not have charges greater than zero in more than five cost centers. We believe that this proposal is appropriate because we are not introducing new costs into the relative weight calculation; we are only proposing to make use of more refined, granular costs by breaking out implantable devices from the Supplies and Equipment CCR, MRIs and CT scans from the Radiology CCR, and cardiac catheterization from the Cardiology CCR. Furthermore, because we are proposing to make use of more refined cost report data for these cost centers, we believe that it is also appropriate to edit the claims with a more refined threshold. We are inviting public comments on the proposal to trim the data used in our relative weight calculations.

- 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.

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 2011 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. (We note that we have made several changes to the table, most importantly, to remove the columns listing the cost centers from the CMS Form 2552–96 cost reports. Because we are proposing to use data from FY 2011 cost reports, which were filed on the CMS Form 2552–10, the columns referencing the CMS Form 2552–96 cost report are no longer relevant. We also have updated and refined the table to reflect the proposed 19 CCRs, instead of the current 15, and we have made some minor corrections to revenue codes and cost report cost centers that are grouped with each CCR.)

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (worksheet C, part 1, column 5 and line number) form CMS–2552–10	Charges from HCRIS (worksheet C, part 1, column 6 & 7 and line number) form CMS–2552–10	Medicare charges from HCRIS (worksheet D–3, column 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.				

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (worksheet C, part 1, column 5 and line number) form CMS–2552–10	Charges from HCRIS (worksheet C, part 1, column 6 & 7 and line number) form CMS–2552–10	Medicare charges from HCRIS (worksheet D–3, column and line number) form CMS–2552–10
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	D3_HOS_C2_64
			Drugs Charged To Patient.	C_1_C5_73	C_1_C7_64. C_1_C6_73	D3_HOS_C2_73
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, and 0621, 0622, 0623.	Medical Supplies Charged to Patients.	C_1_C5_71	C_1_C7_73. C_1_C6_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294-0299.	DME-Rented	C_1_C5_96	C_1_C7_71. C_1_C6_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME-Sold	C_1_C5_67	C_1_C7_96. C_1_C6_97	D3_HOS_C2_97
Implantable Devices		0275, 0276, 0278, 0624.	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C7_97. C_1_C6_72	D3_HOS_C2_72
Therapy Services	Physical Therapy Charges.	042X	Physical Therapy	C_1_C5_66	C_1_C7_72. C_1_C6_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy.	C_1_C5_67	C_1_C7_66. C_1_C6_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C7_67. C_1_C6_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy	C_1_C5_65	C_1_C7_68. C_1_C6_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C7_65. C_1_C6_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C7_50. C_1_C6_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges.	072X	Delivery Room and Labor Room.	C_1_C5_52	C_1_C7_51. C_1_C6_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges	037X	Anesthesiology	C_1_C5_53	C_1_C7_52. C_1_C6_53	D3_HOS_C2_53
Cardiology	Cardiology Charges	048X and 073X	Electrocardiology	C_1_C5_69	C_1_C7_53. C_1_C6_69	D3_HOS_C2_69
Cardiac Catheterization.		0481	Cardiac Catheterization.	C_1_C5_59	C_1_C7_69. C_1_C6_59	D3_HOS_C2_59
Laboratory	Laboratory Charges	030X, 031X, and 075X.	Laboratory	C_1_C5_60	C_1_C7_59. C_1_C6_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services.	C_1_C5_61	C_1_C7_60. C_1_C6_61	D3_HOS_C2_61
		074X, 086X	Electro-encephalography.	C_1_C5_70	C_1_C7_61. C_1_C6_70	D3_HOS_C2_70
Radiology	Radiology Charges	032X, 040X	Radiology—Diagnostic.	C_1_C5_54	C_1_C7_70. C_1_C6_54	D3_HOS_C2_54
		028x, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology—Therapeutic.	C_1_C5_55	C_1_C7_54. C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan.	C_1_C5_57	C_1_C7_56. C_1_C6_57	D3_HOS_C2_57

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (worksheet C, part 1, column 5 and line number) form CMS–2552–10	Charges from HCRIS (worksheet C, part 1, column 6 & 7 and line number) form CMS–2552–10	Medicare charges from HCRIS (worksheet D–3, column and line number) form CMS–2552–10
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI).	C_1_C5_58	C_1_C7_57. C_1_C6_58	D3_HOS_C2_58
Emergency Room	Emergency Room Charges.	045x	Emergency	C_1_C5_91	C_1_C7_58. C_1_C6_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038x	Whole Blood & Packed Red Blood Cells.	C_1_C5_62	C_1_C7_91. C_1_C6_62	D3_HOS_C2_62
	Blood Storage/Processing.	039x	Blood Storing, Processing, & Transfusing.	C_1_C7_62. C_1_C5_63	C_1_C6_63 C_1_C7_63	D3_HOS_C2_63
Other Services	Other Service Charge.	0002–0099, 022X, 023X, 024X, 052X, 053X. 055X–060X, 064X–070X, 076X–078X, 090X–095X and 099X.				
	Renal Dialysis ESRD Revenue Setting Charges.	0800X 080X and 082X–088X.	Renal Dialysis	C_1_C5_74	C_1_C6_74 C_1_C7_74.	D3_HOS_C2_74
			Home Program Dialysis.	C_1_C5_94	C_1_C6_94 C_1_C7_94	D3_HOS_C2_94
	Outpatient Service Charges.	049X	ASC (Non Distinct Part).	C_1_C5_75	C_1_C6_75 C_1_C7_75	D3_HOS_C2_75
	Lithotripsy Charge	079X.	Other Ancillary	C_1_C5_76	. C_1_C6_76 C_1_C7_76.	D3_HOS_C2_76
	Clinic Visit Charges	051X	Clinic	C_1_C5_90	C_1_C6_90 C_1_C7_90	D3_HOS_C2_90
			Observation beds	C_1_C5_92.01	. C_1_C6_92.01 C_1_C7_92.01.	D3_HOS_C2_92.01
	Professional Fees Charges.	096X, 097X, and 098X.	Other Outpatient Services.	C_1_C5_93	C_1_C6_93 C_1_C7_93	D3_HOS_C2_93
	Ambulance Charges	054X	Ambulance	C_1_C5_95	. C_1_C6_95 C_1_C7_95	D3_HOS_C2_95
			Rural Health Clinic	C_1_C5_88	. C_1_C6_88 C_1_C7_88.	D3_HOS_C2_88
			FQHC	C_1_C5_89	C_1_C6_89 C_1_C7_89.	D3_HOS_C2_89

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2011 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 proposed FY 2014 cost-based relative weights were then normalized by an adjustment factor of 1.6122128377 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to

ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2014 are as follows:

Group	CCR
Routine Days	0.502
Intensive Days	0.423
Drugs	0.193
Supplies & Equipment	0.293
Implantable Devices	0.361
Therapy Services	0.355
Laboratory	0.133
Operating Room	0.225
Cardiology	0.132
Cardiac Catheterization	0.135
Radiology	0.170
MRIs	0.091
CT Scans	0.045
Emergency Room	0.207
Blood and Blood Products	0.371
Other Services	0.399
Labor & Delivery	0.445
Inhalation Therapy	0.187
Anesthesia	0.120

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 this FY 2014 proposed rule, we are proposing to use that same case threshold in recalibrating the proposed MS–DRG weights for FY 2014. Using data from the FY 2012 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some 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 DRGs are identical. The 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 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. In FY 2014, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these low-volume MS–DRGs, we are proposing to compute weights for the low-volume MS–DRGs by adjusting their FY 2013 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.	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

4. Bundled Payments for Care Improvement (BPCI) Initiative

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 health care organizations selected to participate in the BPCI initiative. 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) for a discussion on the BPCI initiative.

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 BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to a hospital's participation within these bundled payment models (that is, as if a hospital were not participating in those models under the BPCI initiative). Therefore, for FY 2014, we are proposing to continue 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.

I. Proposed Add-On Payments for New Services and Technologies

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, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2013 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2014. We refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY–2013–IPPS-Final-Rule-Home-Page.html* for a complete viewing of Table 10 from the FY 2013 IPPS/LTCH PPS final rule.

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 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 (if the estimated costs for the case including the new technology 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.

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 criteria, 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 also 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 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 August 2008 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 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 2015 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 2015, the 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 2014 prior to publication of this FY 2014 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 23, 2012 (77 FR 70163 through 70165), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 5, 2013. 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 2014 new medical service and technology add-on payment applications before the publication of this FY 2014 proposed rule.

Approximately 60 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 over the Internet and received very positive feedback from the public on use of this option. We are considering no longer holding an in-person town hall meeting in Baltimore, MD, and instead holding a virtual town hall meeting that would be live-streamed on the Internet. We are inviting public comments on the possibility of holding a virtual town hall meeting instead of an in-person town hall meeting in Baltimore, MD. Four of the five FY 2014 applicants presented information on their technologies, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of February 26, 2013, in our evaluation of the new technology add-on payment applications for FY 2014 in this proposed rule.

In response to the published notice and the new technology town hall meeting, we received written comments regarding applications for FY 2014 new technology add-on payments. We summarize these comments below or, if applicable, indicate that there were no comments received, at the end of each discussion of the individual applications in this proposed rule.

A number of attendees at the new technology town hall meeting provided comments that were unrelated to ''substantial clinical improvement.'' As explained above and in the **Federal Register** notice announcing the new technology town hall meeting (77 FR 70163 through 70165), the purpose of the new technology town hall meeting was specifically to discuss the

substantial clinical improvement criterion in regard to pending new technology applications for FY 2014. Therefore, we are not summarizing those comments in this proposed rule. Commenters are welcome to resubmit these comments in response to proposals presented in this proposed rule.

3. FY 2014 Status of Technologies Approved for FY 2013 Add-On Payments

a. Auto Laser Interstitial Thermal Therapy (AutoLITT™) System

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. AutoLITT™ is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. The technology can be identified by ICD–9–CM procedure codes 17.61 (Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance), and 17.62 (Laser interstitial thermal therapy [LITT] of lesion or tissue of head and neck under guidance), which became effective on October 1, 2009.

The AutoLITT™ received a 510(k) FDA clearance in May 2009. The AutoLITT™ is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The AutoLITT™ may be used in patients with glioblastoma multiforme brain tumors. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the AutoLITT™ for new technology add-on payments for FY 2011. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27935 through 27936), based on the original information provided by the applicant, we believed that the newness date for the AutoLITT™ began in December 2009. However, as summarized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53345 through 53346), the applicant submitted a public comment (in response to the FY 2013 proposed rule) demonstrating that the AutoLITT™ was first available on May 11, 2010. The manufacturer explained that some of the sterile disposable products were not released from quarantine until May 11, 2010, which prevented the AutoLITT™ from being used prior to May 11, 2010. Therefore, the manufacturer asserted that the first time the AutoLITT™ was available on the market was May 11, 2010. As a result of this information, we continued to make new technology add-on payments for the AutoLITT™ in FY 2013. (We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on this issue).

Consistent with the applicant's clinical trial, the add-on payment is intended only for use of the device in cases of glioblastoma multiforme. Therefore, we limited the new technology add-on payment to cases involving the AutoLITT™ in MS–DRGs 025 (Craniotomy and Endovascular Intracranial Procedures with Major Complications or Comorbidities (MCC)), 026 (Craniotomy and Endovascular Intracranial Procedures with Complications or Comorbidities (CC)), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC or MCC). Cases involving the AutoLITT™ that are eligible for the new technology add-on payment are identified by assignment to MS–DRGs 025, 026, and 027 with a procedure code of 17.61 (Laser interstitial thermotherapy of lesion or tissue of brain under guidance) in combination with a principal diagnosis code that begins with a prefix of 191 (Malignant neoplasm of brain). We note that using the procedure and diagnosis codes above and restricting the add-on payment to cases that map to MS–DRGs 025, 026, and 027 is consistent with information provided by the applicant, which demonstrated that cases of the AutoLITT™ would only map to MS–DRGs 025, 026, and 027. Procedure code 17.62 (Laser interstitial thermotherapy of lesion or tissue of head and neck under guidance) does not map to MS–DRGs 025, 026, or 027 under the GROUPER software and, therefore, is ineligible for new technology add-on payment.

The average cost of the AutoLITT™ is reported as $10,600 per case. Under § 412.88(a)(2) of the regulations, new technology add-on payments are limited 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 AutoLITT™ is $5,300.

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 the AutoLITT™, as stated above, we consider the beginning of the newness period for the device to commence when the AutoLITT™ was first available on May 11, 2010. Because the 3-year anniversary date of the AutoLITT™ entry onto the market will expire May 11, 2013, which is prior to the beginning of FY 2014, we are proposing to discontinue new technology add-on payments for the AutoLITT™ for FY 2014. We are inviting public comments on this proposal.

b. Glucarpidase (Trade Brand Voraxaze®)

BTG International, Inc. submitted an application for new technology add-on payments for Glucarpidase (trade brand 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 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). The cost of Voraxaze® is $22,500 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 $90,000 ($22,500 × 4). Under § 412.88(a)(2), new technology add-on payments are limited 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 $45,000 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)). With regard to the newness criterion for Voraxaze®, as stated above, we consider the beginning of the newness period to commence when Voraxaze® was first available on the market on April 30, 2012. Because Voraxaze® is still within the 3-year newness period, we are proposing to continue new technology add-on payments for this technology for FY 2014. We are inviting public comments on this proposal.

c. DIFICID™ (Fidaxomicin) Tablets

Optimer Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2013 for the use of DIFICID™ tablets. As indicated on the labeling submitted to the FDA, the applicant noted that Fidaxomicin is taken twice a day as a daily dosage (200 mg tablet twice daily = 400 mg per day) as an oral antibiotic. The applicant asserted that Fidaxomicin provides potent bactericidal activity against *C. Diff.,* and moderate bactericidal activity against certain other gram-positive organisms, such as enterococcus and staphylococcus. Unlike other antibiotics used to treat CDAD, the applicant noted that the effects of Fidaxomicin preserve bacteroides organisms in the fecal flora. These are markers of normal anaerobic microflora. The applicant asserted that this helps prevent pathogen introduction or persistence, which potentially inhibits the re-emergence of *C. Diff.,* and reduces the likelihood of overgrowths as a result of vancomycin-resistant Enterococcus (VRE). Because of this narrow spectrum of activity, the applicant asserted that Fidaxomicin does not alter this native intestinal microflora.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27939 through 27941), we expressed concern that DIFICID™ may not be eligible for new technology add-on payments because eligibility is limited to new technologies associated with procedures described by ICD–9–CM codes. We further stated that drugs that are only taken orally (such as DIFICID™) may not be eligible for consideration for new technology add-on payments because there is no procedure associated with these drugs and, therefore, no ICD–9–CM code(s). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53350 through 53358), after consideration of the public comments received, we revised our policy to allow the use of National Drug Codes (NDCs) to identify oral medications that have no inpatient procedure for the purposes of new technology add-on payments. The revised policy is effective for payments for discharges occurring on or after October 1, 2012. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on this issue.

With regard to the newness criterion, Fidaxomicin was approved by the FDA on May 27, 2011, for the treatment of CDAD in adult patients, 18 years of age and older. In the FY 2013 IPPS/LTCH PPS final rule, we established that the beginning of the newness period for this technology is its FDA approval date of May 27, 2011.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for DIFICID™ and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved DIFICID™ for new technology add-on payments for FY 2013. Cases of DIFICID™ are identified with ICD–9–CM diagnosis code 008.45 (Intestinal infection due to *Clostridium difficile*) in combination with NDC code 52015–0080–01. Providers must report the NDC on the 837i Health Care Claim Institutional form (in combination with ICD–9–CM diagnosis code 008.45) in order to receive the new technology add-on payment. According to the applicant, the cost of DIFICID™ is $2,800 for a 10-day dosage. The average cost per day for DIFICID™ is $280 ($2,800/10). Cases of DIFICID™ within the inpatient setting typically incur an average dosage of 6.2 days, which results in an average cost per case for DIFICID™ of $1,736 ($280 × 6.2). Under § 412.88(a)(2), new technology add-on payments are limited 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 FY 2013 for DIFICID™ is $868.

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 DIFICID™, as stated above, we consider the beginning of the newness period to commence when DIFICID™ was first approved by the FDA on May 27, 2011. Because the 3-year anniversary date of DIFICID™ will occur in the second half of the fiscal year (after April 1, 2014), we are proposing to continue new technology add-on payments for DIFICID™ for FY 2014. We are inviting public comments on this proposal.

d. 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 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 are 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 do 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), new technology add-on payments are limited 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.

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)). With regard to the newness criterion for the Zenith® F. Graft, as stated above, we consider the beginning of the newness period to commence when the Zenith® F. Graft was approved by the FDA on April 4, 2012. Because the Zenith® F. Graft is still within the 3-year newness period, we are proposing to continue new technology add-on payments for this technology for FY 2014. We are inviting public comments on this proposal.

4. FY 2014 Applications for New Technology Add-On Payments

We received five applications for new technology add-on payments for FY 2014.

a. 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.

The applicant expects to receive FDA approval for Kcentra™ in the second quarter of 2013. The technology is not described by any current ICD–9–CM procedure codes. The applicant applied for a new ICD–9–CM procedure code for consideration at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee Meeting. More information on this request can be found on the CMS Web site at: *http://cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2013-03-05-Meeting Materials.html*. We note that any final decisions on new codes approved at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting will be included in the ICD–9–CM code addendum posted on the CMS Web site in June 2013 at: *http://cms.hhs.gov/Medicare/Coding/ICD9Provider DiagnosticCodes/addendum.html*. In addition, code revisions that were discussed at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting but that could not be finalized in time to include them in the tables for this proposed rule will be included in the appropriate table for the final rule (the tables for both the proposed rule and the final rule are available via the Internet on the CMS Web site).

We note that we are concerned that Kcentra™ may be substantially similar to FFP and/or Vitamin K therapy. If so, Kcentra™ would not meet the newness criterion because costs associated with FFP and/or Vitamin K therapy are already reflected within the MS–DRGs. 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 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 the criteria above, 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 first criterion, we believe that both FFP and Kcentra™ use the same mechanism of action of Vitamin K dependent coagulation to reverse the anti-coagulation effects of warfarin. With respect to the second criterion, we believe that cases involving both FFP and Kcentra™ would be assigned to the same MS–DRGs. Finally, with respect to the third criterion, we believe that both technologies treat the same disease and patient population. Specifically, the patient population for both Kcentra™ and FFP are patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Delay of treatment of these patients can lead to an increase in complications as well as an increase of the severity of the bleed. Although FFP needs to thaw for a couple of hours before it can be administered (thus delaying treatment) compared to Kcentra™, which can be used instantly, we believe that both Kcentra™ and FFP treat the same patient population. Based on evaluation of the similarity criteria, it appears that Kcentra™ is

substantially similar to FFP. Therefore, Kcentra™ may not be considered ''new'' for purposes of new technology add-on payments. We are inviting public comments regarding whether Kcentra™ is substantially similar to existing technologies and whether Kcentra™ meets the newness criterion.

According to the applicant, the technology is eligible to be used across all MS–DRGs. To demonstrate that it meets the cost criterion, the applicant searched the FY 2011 MedPAR file (across all MS DRGs) for cases reporting a primary or secondary diagnosis of E934.2 (Adverse events due to anticoagulants), V58.61 (Long term (current) use of anticoagulants), or 964.2 (Poisoning by anticoagulants) in combination with procedure code 99.07 (Transfusion of the serum). The applicant believed that this combination identified cases that suggest the use of a Vitamin K antagonist therapy as well as a major bleed.

The applicant found 66,749 cases across all MS–DRGs and noted that 18 percent of all cases would map to MS–DRGs 377 (Gastrointestinal Hemorrhage with MCC), 378 (Gastrointestinal Hemorrhage with CC), and 379 (Gastrointestinal Hemorrhage without CC/MCC), while the top 20 MS–DRGs would account for 41 percent of all cases. The applicant standardized charges (for all 66,749 cases) and removed charges for FFP therapy, which equated to a case-weighted average standardized charge per case of $49,748. The applicant calculated a case-weighted threshold of $46,068 across all MS–DRGs. The applicant asserted that the average case-weighted standardized charge per case without including charges for Kcentra™ exceeded the case-weighted threshold of $46,068. Therefore, the applicant maintained that it meets the cost criterion. We are inviting public comments regarding whether Kcentra™ meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analysis.

With regard to substantial clinical improvement, according to the applicant, Kcentra™ is the first prothrombin complex concentrate (PCC) that will be FDA-approved for rapid warfarin reversal in patients experiencing an acute major bleed. The manufacturer maintained that Kcentra™ represents a substantial clinical improvement in the treatment of patients with acute severe bleeding who require immediate reversal of their Vitamin K antagonist (VKA) therapy by (1) providing a rapid, beneficial resolution of the patient's blood clotting factor deficiency, (2) decreasing the risk of exposure to blood borne pathogens, and (3) reducing the rate of transfusion-associated complications.

The applicant cited its pivotal study (a noninferior, randomized clinical trial) [3] and noted that Kcentra™ was able to reverse the effects of warfarin to a target International Normalized Ratio (INR) of less than or equal to 1.3 within 30 minutes in 62 percent of patients compared to less than 10 percent success for plasma. Also, serum levels of the key coagulant and anti-thrombotic proteins were normalized in less than an hour with Kcentra™, but remained depressed with plasma for hours.

The applicant also explained that Kcentra™ undergoes a dedicated pathogen removal process and plasma does not. The applicant asserted that this drastically reduces the risk of transmitting both known and unknown blood borne pathogens. The applicant cited a retrospective analysis of scientific publications [4] on the use of Kcentra™ in the European Union (EU), including the pharmacovigilance database from 1996 through 2008. The applicant noted that an estimated 350,000 patients have been treated with Kcentra™ (known as Beriplex in the EU) with no cases of viral transmission.

The applicant also stated that, in the United States, blood suppliers follow a strict set of regulations for screening and testing the blood supply, but these tests and donor questionnaires do not account for emerging pathogens that could contaminate the blood supply. The applicant explained that parasitic infections and diseases (such as babesiosis and Chaga's disease) have already been documented in U.S. patients as a result of transfusion. However, there is no screening test to date for some of these parasitic infections and diseases. The applicant believed that the multi-step manufacturing process for Kcentra™, including heat treatment and nanofiltration, reduces the risk of transmitting such infections and diseases.

The applicant also noted that another benefit of Kcentra™ is the ability to rapidly prepare and administer the product in an emergency situation. In addition to the benefit of room temperature storage, Kcentra™ can be rapidly reconstituted. In the clinical study, the applicant found that the average administration time for Kcentra™ was less than 30 minutes. However, the applicant stated, other treatments such as FFP and intravenous Vitamin K therapies act slowly, and FFP can be difficult to use. The applicant explained that FFP therapy requires blood-type matching, usually requires thawing, and is often located away from the point of care. The applicant also cited a study [5] that demonstrated the median time from time of diagnosis to plasma infusion was 90 minutes, which did not include time to infuse the plasma which can take hours.

The applicant further noted that essential blood coagulation factors in one vial of Kcentra™ are approximately 25 times more concentrated than the equivalent plasma dose. According to the applicant, this translated to an infusion volume that was 87 percent greater in the plasma group of patients as seen in the pivotal study. The applicant explained that high transfusion volumes of treatments such as FFP therapy can lead to transfusion-associated circulator overload (TACO). According to the applicant, when TACO occurs, acute left ventricular failure may occur resulting in shortness of breath, tachypnea (rapid breathing), and other harmful effects.

Finally, the applicant noted that Kcentra™ is the standard of care in the new guidelines issued by the American College of Chest Physicians (ACCP). In addition, the applicant noted that the American Association of Blood Banks (AABB) stated that plasma should no longer be used to reverse warfarin in bleeding patients when specific factor concentrates are available.

In conclusion, the applicant maintained that Kcentra™ represents a substantial clinical improvement over existing technologies. We are inviting public comments regarding whether Kcentra™ meets the substantial clinical improvement criterion.

We note, if Kcentra™ were to be approved for new technology add-on payments, we do not believe such payments would be available with respect to discharges for which the hospital receives an add-on payment for 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

[3] Sarode R, et al., Efficacy and Safety of a Four Factor Prothrombin Complex Concentrate in Patients on Vitamin K Antagonists Presenting with Major Bleeding: A Randomized, Plasma Controlled, Phase IIIb Study. Circulation. Submitted October 31, 2012. Copy to be provided upon acceptance.

[4] Hanke A, et al., Efficacy and Long-Term Safety of a Pasteurized Nanofiltrated Prothrombin Complex Concentrate (BERIPLEX® P/N), 2009, J Thromb Haemost, Vol. 7 (Suppl.2) PP–WE–697.

[5] Goldstein, Joshua N., et al., Timing of Fresh Frozen Plasma Administration and Rapid Correction of Coagulopathy in Warfarin-Related Intracerebral Hemorrhage, Stroke 37.1 (2006):151–155.

payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section)'' 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 blood clotting factor to Medicare beneficiaries who have hemophilia and are hospital inpatients are paid separately from the IPPS. (For information on how the clotting factor add-on payment is made, we refer readers to section 20.7.3 of Chapter Three of the Medicare Claims Processing Manual, which can be downloaded from the CMS Web site at: *http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*) If Kcentra™ is approved by FDA as a blood clotting factor, we believe that it may be eligible for clotting factor add-on payments when administered to Medicare beneficiaries with hemophilia. CMS would make an add-on payment for Kcentra™ for such discharges in accordance with our policy for payment of blood clotting factor, and it 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 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 point out that new technology add-on payments are based on the operating costs per case relative to the prospective payment rate as described in 42 CFR 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.

If Kcentra™ were to be approved for new technology add-on payments, we believe that hospitals may only receive that add-on payment for discharges where Kcentra™ is an operating cost of inpatient hospital services. In other words, we do not believe a hospital could 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 could be eligible for a new technology add-on payment because Kcentra™ would not be excluded from the operating costs of inpatient hospital services. Therefore, we do not believe that discharges where the hospital receives a clotting factor add-on payment are eligible for a new technology add-on payment for the blood clotting factor.

To summarize, we believe it would be inappropriate to make an add-on payment for new technology for a blood clotting factor when a blood clotting factor add-on payment has been made. We welcome public comment on our proposal to only make new technology add-on payments for Kcentra™ in cases when it is included in the operating costs of inpatient hospital services (that is, when no add-on payment is made for clotting factor).

b. 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 Retinal Prosthesis 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. Currently there are no other approved treatments for patients with severe to profound RP. The Argus® II System has an IDE number of G050001 and is a Class III device. There are no existing ICD–9–CM or ICD–10–CMS/PCS codes for the implantation of a retina prosthesis. The applicant applied for three new ICD–9–CM procedure codes for consideration at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. More information on this request can be found on the CMS Web site at: *http://cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2013-03-05-MeetingMaterials.html*. We note that any final decisions on new codes approved at the March 5, 2013 Coordination and Maintenance Committee meeting will be included in the ICD–9–CM code addendum posted on the CMS Web site in June 2013 at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum.html*. In addition, code revisions that were discussed at the March 5, 2013 Committee meeting but that could not be finalized in time to include them in the tables for this proposed rule will be included in the appropriate table in the final rule (the tables for both the proposed rule and the final rule are made available via the Internet on the CMS Web site). We are inviting public comments on whether the Argus® II System meets the newness criterion.

With regard to the cost criterion, the applicant identified all discharges from claims in the FY 2011 MedPAR file for MS–DRGs 116 (Intraocular Procedures with CC/MCC) and 117 (Intraocular Procedures without CC/MCC) with the presence of ICD–9–CM procedure code 14.73 (Anterior vitrectomy), or 14.74 (Posterior vitrectomy). (We note that because no procedure code exists for this technology, these cases would include patients that are not eligible for or would not otherwise receive this technology.) The applicant found 199 cases (47.6 percent of all cases) in MS–DRG 116 and 219 cases (52.3 percent of all cases) in MS–DRG 117. This resulted in an average charge per case of $40,957 for MS–DRG 116 and $20,621 for MS–DRG 117, equating to a case-weighted average charge per case of $24,011.

The applicant then standardized the charges using the FY 2011 final rule impact file and converted the cost of the device to a charge by dividing the operating costs by a CCR of 0.50 (which equates to a 100 percent markup). Although the applicant submitted data related to the estimated cost of the Argus® II System, the applicant noted that the cost of the technology was proprietary information. The applicant then added the charges related to the device to the case-weighted average standardized charge per case and determined a final case-weighted average standardized charge per case of $311,180. Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 116 and 117 was $30,328 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceed the case-weighted threshold amount, the applicant maintained that the Argus® II System would meet the cost criterion.

We note that, although we cannot disclose the cost of the technology, the device is very costly. Because of its high costs, the technology would easily exceed the case-weighted threshold. In addition, because of the high cost of the device it is likely that claims with the device would receive an outlier payment. The applicant anticipates that approximately 65 Argus® II Systems will be sold in FY 2014, of which approximately 50 systems would be provided to Medicare patients. The target disease population is extremely limited as required and supported by the HDE application. Most patients for whom this technology is indicated may be eligible for Medicare based on their age or a disability that is associated with profound blindness.

We also note that these types of procedures are often performed in the outpatient setting. We are concerned that if new technology add-on payments were to be approved, this would serve as a financial incentive to inappropriately shift utilization from an outpatient to an inpatient setting, although medical review may result in very few of these cases being paid as inpatient hospital services if the patient can be appropriately treated as an outpatient. We continue to emphasize that it is critical that physicians use their clinical judgment in determining the medical necessity of an inpatient admission and stress that care should be provided in the appropriate setting. We are inviting public comments on whether the Argus® II System meets the cost criterion, particularly based on the assumptions and methodology used in the applicant's analysis. We also have general concerns relating to the descriptions of the medical necessity of performing this procedure on an inpatient basis. Therefore, we are inviting public comments to further our understanding regarding whether approving new technology add-on payments for the Argus® II System would create a financial incentive that

would shift utilization inappropriately from an outpatient to an inpatient setting.

With regard to the substantial clinical improvement criterion, the Argus® II System is intended to provide electrical stimulation of the retina to induce visual perception in blind patients with the indication of severe to profound RP with bare or no light perception in both eyes. According to the applicant, an estimated 1 in 3,037 Americans suffers from RP, and the incidence of people with severe to profound RP is significantly lower. According to the applicant, the need for treatments for RP is high, given the impact of loss of vision.

According to the applicant, numerous experimental research programs are currently underway to slow, stop, or reverse the progress of RP, including gene therapy, tissue and cell transplants, and some pharmacologic neuroprotection therapies. However, these approaches so far have had fairly limited success in treating RP patients, and some approaches are intended for an extremely small segment of the RP population. Currently there are no other approved treatments for patients with severe to profound RP. Therefore, the Argus® II device treats a patient population that has no other treatment options.

The applicant submitted the results of a clinical trial to demonstrate substantial clinical improvement. This clinical trial enrolled 30 patients. The median age of patients was 57.9 years at the time of implantation and the range was 28 to 77 years of age. Thirty percent of the patients were female, and 70 percent were male. All of the patients had bare or no light perception in both eyes. Fourteen of the patients were Medicare eligible. As part of the methods for the study, the applicant stated that while working within the framework of clinical trials for other ophthalmic devices, the manufacturer and its team of scientific advisors selected or designed several tests that would address the main elements of the system that should be assessed for these types of devices—visual function (that is, how the eye as an organ works [for example, visual acuity]), functional vision (that is, how the patient performs in vision-related activities of daily living), and quality of life. The endpoints that were selected provided a mixture of objective and subjective data. The study design was strengthened by the fact that controlled observations could be obtained by performing assessments with the Argus® II System ''on'' and ''off'' (that is, control was available at each time point).

According to the applicant, there were no unexpected adverse events. Non-serious adverse events represented the majority of events. The safety review concluded that the Argus® II System has a reasonable safety profile for an ophthalmic device that requires vitreoretinal surgery to implant. In addition, the applicant noted that the device can be extracted and is reversible. The Argus® II System provided all 30 patients with benefit as measured by high-contrast visual function tests. The applicant stated that the degree of benefit varied from patient to patient and provided the following results:

- All subjects were able to see visual percepts when the Argus® II System was electrically activated.
- On the Square Localization Test (that is, object localization), patients (on average) performed better with the system ''on'' rather than ''off'' at all follow-up time points. At 24 months, on average, patients missed the target by approximately 50 pixels with the system ''on'' versus approximately 250 pixels with the system ''off''.
- On the Direction of Motion Test, which tested the patients' ability to determine the direction of a moving bar, patients had higher mean accuracy with the system ''on'' than they did with the system ''off'' at all follow-up time points, indicating that the Argus® II System improved their performance on a spatial vision task. At 24 months, the mean response error was approximately 60° with the system ''on'' versus more than 80° with the system ''off''. According to the applicant, this is nearly the error expected by chance.
- On the Grating Visual Acuity Test, which assessed the patients' visual acuity using the principles of acuity charts designed for extremely low vision patients, 27 percent of the patients were able to score on the scale (between 1.6 and 2.9 log MAR) at least once with the system ''on'', while none of the Argus® II patients were able to score on the scale with the system ''off.''
- A large number of patients were able to recognize large letters and numbers with the system ''on'' (but not with the system ''off''), and some of the patients were able to read short words. The median percent correct with the system ''on'' was approximately 50 percent higher than with the system ''off.''
- The trial also measured objectively-scored functional vision tests. The patients performed better with the Argus® II System ''on'' versus ''off'' on orientation and mobility tests (finding a door and following a line) and on functional vision tasks (sorting white, black, and grey socks, following an outdoor sidewalk, and determining the direction of a person walking by).
- Analysis of the Functional Low-vision Observer Rated Assessment (FLORA) results showed that three-quarters of the patients received a positive benefit in terms of well-being and/or functional vision, while none of the patients experienced a negative effect.

We note that we are concerned that the study did not have pre-specified endpoints and changed measurements mid trial. In addition, we are concerned about the reliability of the measures used for the tests and the inconsistency of the results across different patients, which lead us to question the long-term benefits associated with this device. We are inviting public comments on whether the Argus® II System meets the substantial clinical improvement criterion, specifically in regard to the measures used in the study and the lack of pre-specified endpoints.

We received two comments on the Argus®II System during the town hall meeting's public comment period. These comments are summarized below.

Comment: Several commenters supported approving the Argus® II System for new technology add-on payments. One commenter, a society of retina specialists, stated that the Argus® II System is the first and only approved treatment in the United States for patients suffering from severe to profound cases of retinitis pigmentosa with bare or no light perception in both eyes. The commenter explained that while the Argus® II System does not restore vision, it provides visual information that can range, depending on the patient, from light detection to form detection. The commenter asserted that, for patients with bare or no light perception, even limited restoration of vision can make a substantial difference, restoring a patient's ability to visually connect and interact with others and providing greater independence.

Another commenter, a foundation for supporting blindness, stated that it is essential that CMS is progressive in making therapies like the Argus® II System accessible for these patients who have no other treatment alternatives. The commenter recommended approving the Argus® II System for new technology add-on payments. The commenter noted that for patients with rare retinal diseases like retinitis pigmentosa, the Argus® II System represents the first approved breakthrough to help restore sight and improve quality of life.

Response: We appreciate the commenters' support. We considered

these comments presented during the town hall meeting's public comment period in the development of this proposed rule. As stated above, we are inviting additional public comments on whether the Argus® II System meets the substantial clinical improvement criterion, specifically in regard to the measures used in the study and the lack of pre-specified endpoints.

c. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2014 for the use of the RNS® System. 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 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® 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 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 or helpful for 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 with medically intractable partial onset seizures. The applicant anticipates FDA premarket approval of the RNS® System in the second quarter of 2013.

The following ICD-9-CM procedure codes are used to identify this technology: 01.20 (Cranial implantation or replacement of neurostimulator pulse generator); 01.29 (Removal of cranial neurostimulator pulse generator); and 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)). We are inviting public comments on whether the technology meets the newness criterion.

With regard to the cost criterion, the applicant stated that cases eligible for the RNS® System would map to MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex Central Nervous System Principal Diagnosis without MCC). The applicant further stated that while it was possible for cases to occur in MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant), it would be extremely rare because the applicant believed that these major complications and/or comorbidities would probably preclude a patient from receiving the technology because the technology is an elective procedure.

The applicant submitted two analyses to demonstrate that it meets the cost criterion. For the first analysis, the applicant used clinical trial claims data collected in the RNS® System Pivotal Clinical Investigation to calculate the anticipated average standardized charge. The applicant maintained that this analysis best represents the anticipated charges for the technology because it is based on actual cases treated with this technology. The applicant analyzed 163 claims from 28 hospitals participating in the clinical trial. Five claims from one site were excluded because no hospital-specific information regarding standardization was available. The resulting 158 claims included dates of service ranging from May 2006 through May 2009. The average charge per case for these 158 claims was $54,961.

The applicant then standardized the charges for each claim. The applicant noted that it was not necessary to remove any charges from these claims because the technology was provided at no charge in the trial. After standardizing the charges, the applicant inflated each claim using the Consumer Price Index for Inpatient Hospital Services (CPI–IP) to inflate the data to the same period. Specifically, because the publicly available FY 2011 MedPAR data do not identify the month of the discharge on inpatient claims but identify the calendar quarter, the applicant used a mid-month convention to determine the relevant monthly CPI–IP for each calendar quarter. The applicant then calculated the percentage change from the relevant quarter to the quarter of the most recently available CPI–IP, which was the August 2012 CPI–IP. Specifically, the applicant used the following assumptions:

FY 2011 Calendar quarter	Midpoint of quarter	CPI IP	Percent change to August 2012
Q4 2010	Nov–10	227.186	9.54
Q1 2011	Feb–11	232.933	6.84
Q2 2011	May–11	235.567	5.64
Q3 2011	Aug–11	237.219	4.91
Most recent as of application	Aug–12	248.856	.....

Source as cited by applicant: Bureau of Labor Statistics' Web site, accessed October 15, 2012; Base Period: December 1996 = 100.

After inflating the charges, the applicant estimated charges for the RNS® System by multiplying the device cost to the hospital by an anticipated hospital markup of 100 percent, or conversely by dividing the device cost by a CCR of 0.50. The applicant based its estimated CCR on four analyses. First, the applicant reviewed the 2007 and 2008 reports prepared by RTI for CMS on charge compression, which found that the national aggregate CCR for devices and implants was 0.43 and 0.467 in the respective reports. Second, the applicant queried hospitals participating in the RNS® System Pivotal trial, and these queries yielded a mean and median CCR for implantable

devices of 0.37 and 0.36, respectively. Third, the applicant reviewed data from the (all payor) Premier database for cases performed in 2000 through 2010 that reported ICD–9 CM procedure codes 02.93 and/or 86.95 on a claim and calculated a mean and median CCR for implanted leads and neurostimulators of 0.50 and 0.44, respectively. The applicant then reviewed other discussions of past new technology add-on payment applications published in the **Federal Register** and noted that other applicants used lower CCRs (higher markups) for implanted devices than the 0.50 CCR used in the applicant's analyses.

Using this approach, the applicant added the anticipated hospital charge for the implantable RNS® System to the inflated average standardized charge per case and determined a final inflated average standardized charge per case of $121,990. Although the applicant submitted data related to the estimated cost of the RNS® System, the applicant noted that the cost of the technology was proprietary information. Using the FY 2014 Table 10 thresholds, the threshold for MS–DRG 024 is $78,039. Because the final inflated average standardized charge per case of $121,990 for MS–DRG 024 exceeds the threshold amount, the applicant maintained that the RNS® System would meet the cost criterion.

In the second analysis, which the applicant characterizes as supplementary, the applicant searched the FY 2011 MedPAR file for cases reporting the combination of ICD–9–CM procedures codes 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and 86.95 (Insertion or replacement of multiple array neurostimulator pulse generator, not specified as rechargeable), or the combination of ICD–9–CM procedures codes 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and 01.20 (Cranial implantation or replacement of neurostimulator pulse generator) that mapped to MS–DRG 024.

The applicant found 565 claims reporting the combination of ICD–9–CM procedures codes 02.93 and 01.20, and pointed out that these cases were coded with procedure code 01.20 in error because no new RNS® System implantations occurred after May 2009. The applicant analyzed these 565 claims and found that more than 90 percent of these cases had a primary or secondary diagnosis of Parkinson's disease, essential tremor, or dystonia. These diagnoses are FDA-approved indications for deep brain stimulation (DBS). In addition, the applicant noted that the total covered charges for these cases were less than the estimated charges for a full DBS system and hypothesized that these cases did not represent implantation of a full DBS system but implementation of leads only. The applicant contacted two hospitals that reported claims where total covered charges were less than the charges for a full DBS system, and the hospitals confirmed that their claims represented lead implantation alone. Therefore, for this second analysis, the applicant included all of the cases in MS–DRG 024 reported with a combination of ICD–9–CM procedures codes 02.93 and 86.95 and all of the cases in MS–DRG 024 reported with ICD–9–CM procedures codes 02.93 and 01.20 where the covered charges were greater than or equal to the estimated charges of a full DBS system. The applicant maintained that 485 claims from 130 providers met these criteria and that these data represented claims from the fourth calendar quarter of 2010 through the third calendar quarter of 2011, or FY 2011. Based on this assumption, the applicant calculated an average charge per case of $60,955. The applicant then removed DBS charges from the average charge per case. The applicant estimated charges for DBS and maintained that the average cost for a DBS system was $25,979. Similar to its first analysis, the applicant assumed a CCR of 0.50, or 100 percent markup, which resulted in estimated charges for DBS of $51,958. After removing DBS charges, the applicant standardized charges and then inflated the charges to the current period using the same methodology in the first analysis. The applicant then added charges for the RNS® System and determined a final inflated average standardized charge per case of $118,408. As noted above, although the applicant submitted data that related to the estimated cost of the RNS® System, the applicant noted that the cost of the technology was proprietary information. Using the FY 2014 Table 10 thresholds, the threshold for MS–DRG 024 is $78,039. Because the final inflated average standardized charge per case of $118,408 for MS–DRG 024 exceeds the threshold amount, the applicant maintained that the RNS® System would meet the cost criterion.

Under either analysis, the applicant maintained that the final inflated average standardized charge per case would exceed the case-weighted threshold. We are inviting public comments on whether the RNS® System meets the cost criterion, particularly based on the assumptions and methodology used in the applicant's analyses.

With regard to substantial clinical improvement, as previously stated, some patients with partial onset seizures may not be able to control their seizures with antiepileptic medications, VNS, or with surgical removal of the seizure focus. The applicant stated that the RNS® System provides treatment for those patients who fail treatment with antiepileptic medications, or fail VNS therapy and are ineligible for respective surgery due to the extent and/or location of the seizure, or patients who do not elect surgery. According to the applicant, the RNS® System clinical trials provide Class I evidence that treatment with the RNS® System substantially reduces disabling seizures in patients with severe epilepsy who have tried and failed treatment with antiepileptic medications, and in many cases VNS or epilepsy surgery. The applicant maintained that the results from their clinical trials demonstrate significant and sustained improvements in health outcomes over the controlled period and over the long term.

The applicant stated that their pivotal trial met its primary effectiveness endpoint by proving that there was a statistically significant greater reduction in seizures in the treatment group compared to the control group ($p = 0.012$). Significant improvements at 1 and 2 years post-implant included:

- A significant reduction in disabling seizures of 44 percent and 53 percent at 1 and 2 years, respectively; and
- Significant improvements in overall quality of life as well as individual quality of life measures including memory, language, attention, concentration and medication effects.

The applicant asserted that there was no negative effect of treatment with the RNS® System on neuropsychological function (including verbal functioning, visual-spatial processing, and memory) or mood. The applicant concluded that the RNS® System Pivotal trial provides Class I evidence that responsive cortical stimulation is effective in significantly reducing seizure frequency in adults with 1 or 2 seizure foci who have failed 2 or more antiepileptic medication trials. The applicant stated that experience across all of the RNS® System trials demonstrates the reduction in seizure frequency of disabling partial seizures improves over time. In addition, the applicant noted that sustained improvements were also seen in quality of life. Finally, the applicant noted that safety and tolerability compares favorably to alternative treatments such as

antiepileptic medications, VNS, and epilepsy surgery.

With regard to the substantial clinical improvement criterion, we are concerned that the average age of patients in the applicant's study was 35 years. Although the applicant maintained that 31 percent of the patients enrolled in the pivotal trial were Medicare beneficiaries, we are unsure of the extent to which this technology would be used by Medicare beneficiaries due to the relatively young age of the majority of patients enrolled in the pivotal trial. We also are concerned that further clarification on how the RNS® System compares to other neurostimulation treatments was not provided by the applicant. The applicant did provide the following comparison of VNS to the RNS® System:

KEY DIFFERENCES BETWEEN THE RNS® SYSTEM AND DBS AND VNS SYSTEMS

	RNS® System	Deep brain stimulator (DBS)	Vagus nerve stimulator (VNS)
Type of stimulation	Closed loop: responsive	Open loop: scheduled.	
Stimulation time/day	About 5 minutes		
Stimulation target	Cortical; varies according to seizure focus.	Deep brain nuclei	Ascending vagus nerve.
Neurostimulator	Cranially implanted	Subcutaneously (pectorally) implanted.	
Programming changes	According to clinical and electrographic response.	According to clinical response.	
Information from device	Device data, detections, stimulations and electrocorticograms.	Device data.	
Physician data review	At time of programming as well as online access to stored data.	At time of programming.	

Because the applicant included claims with DBS in one of its cost analyses, we believe that the similarities and differences between DBS and the RNS® System may also be relevant under the substantial clinical improvement criterion. In addition, we are concerned that the time period in the clinical trial may not be sufficient to confirm durability. In the RNS® System Pivotal Clinical Investigation, the primary effectiveness endpoint considered seizure frequency over the last 3 months of the blinded period of the trial. We note that the applicant is currently conducting a 5-year study. We are inviting public comments on whether the RNS® System meets the substantial clinical improvement criterion, particularly in regard to the degree in which the technology would be used by Medicare beneficiaries, the comparison to other neurostimulation treatments, and its durability.

We received two comments on the RNS® System during the town hall meeting's public comment period. These comments are summarized below.

Comment: One commenter stated that it looked forward to the RNS® System's commercial availability and encouraged CMS to approve the RNS® System for new technology add-on payments. The commenter noted that the benefits of the RNS® System therapy include a significant reduction in seizure frequency and severity, and for some patients, extended periods of seizure freedom. The commenter asserted that this reduction in seizure frequency improves over time and is sustained over several years of follow-up, and can result in improved cognition and a better quality of life. The commenter added that, most impressively, these positive results were achieved with no chronic side effects from stimulation. The commenter also noted that a significant number of these individuals are eligible for Medicare due to their disability.

Another commenter stated that the pivotal trial findings, in both the blinded period and the open-label period, have provided compelling support for what had previously been an only theoretical concept for non-ablative intervention. The commenter explained that those patients with seizure foci in eloquent areas or with hi-hippocampal seizure onset, the most difficult patient cohort to address, have been well-suited to RNS and often substantially benefited from this intervention. The commenter noted that in the functional and stereotactic neurosurgical community, the most exciting and compelling advances have arisen from those non-resective strategies by which maladaptive pathophysiology and its symptoms have been ameliorated by targeted electrical stimulation and neural function preserved with the NeuroPace experience—the most compelling in epilepsy.

The commenter concluded with the following: the RNS® System has had a remarkable and reassuring safety track record; the surgery for its implementation is comparable to that of deep brain stimulation system placement; the permanent and serious morbidity have been extremely low and the serious and life-threatening risks associated with medically intractable epilepsy, in comparison, are generally underappreciated and substantially higher.

Response: We appreciate the commenters' support. We considered these comments presented during the town hall meeting's public comment period in the development of this proposed rule. As stated above, we are inviting additional public comments on whether the RNS® System meets the substantial clinical improvement criterion, particularly in regard to the degree in which the technology would be used by Medicare beneficiaries, the comparison to other neurostimulation treatments, and its durability.

d. 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). We are inviting public comments regarding how the Zilver® PTX® meets the newness criterion.

With regard to the cost criterion, the applicant believed that cases of superficial femoral arteries typically map to MS–DRGs 252 (Other Vascular Procedures with MCC), 253 (Other Vascular Procedures with CC), and 254 (Other Vascular Procedures without CC/MCC). The applicant searched the FY 2010 MedPAR file for cases reporting procedure code of 39.90 (Insertion of non-drug-eluting peripheral vessel stents) in combination with a diagnosis code of 440.20 (Atherosclerosis of the extremities, unspecified), 440.21 (Atherosclerosis of the extremities, with intermittent claudication), 440.22 (Atherosclerosis of the extremities with rest pain), 440.23 (Atherosclerosis of the extremities with ulceration), or 440.24 (Atherosclerosis of the extremities with gangrene). The applicant noted that the Zilver® PTX® is available in an 80 mm size and is approved for lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 9 mm and total lesion lengths up to 140 mm per limb. The applicant further noted that bare metal stents typically are available up to lengths of 200 mm. Therefore, in order to target cases eligible for the Zilver® PTX®, the applicant believed it was only appropriate to target those cases with one or two bare metal stents. The applicant was able to identify the amount of stents used per claim by searching for ICD–9–CM procedure codes 00.45 (Insertion of one vascular stent) and 00.46 (Insertion of two vascular stents). The applicant submitted two methodologies: one with cases that received one bare metal stent and the other with cases that received one or two bare metal stents.

Under the first methodology (one bare metal stent), the applicant found 2,062 cases (or 19.7 percent of all cases) in MS–DRG 252, 3,385 cases (or 32.3 percent of all cases) in MS–DRG 253, and 5,019 cases (or 48 percent of all cases) in MS–DRG 254. The average charge per case was $89,194 for MS–DRG 252, $67,965 for MS–DRG 253, and $46,539 for MS–DRG 254, equating to a case-weighted average charge per case of $60,855.

The case-weighted average charge per case above does not include charges related to the Zilver® PTX®. Therefore, it is first necessary to remove the amount of charges related to the non-drug-eluting peripheral vessel stent and replace them with charges related to the Zilver® PTX®. The applicant multiplied the use of the single stent used per case by the average market price for non-drug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing the results by the hospital-specific CCR (from the FY 2010 IPPS impact file). The applicant removed the appropriate amount of charges per case and then standardized the charges per case.

Because the applicant used FY 2010 MedPAR data, it was necessary to inflate the charges from FY 2010 to FY 2013. Using data from the Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 7 percent. 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 above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study [6]. The applicant believed that it is appropriate to use data from the clinical study (to determine the average amount of stents used per case) rather than the actual data from the claims because the length of a non-drug-eluting peripheral vessel stent typically ranges from 80mm to 120 mm, while the length of the Zilver® PTX® is 80 mm (which could cause a variance in the actual amount of stents used per case when using the Zilver® PTX®). The applicant then multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the hospital-specific CCR (from the FY 2010 IPPS impact file). The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final inflated case-weighted average standardized charge per case of $58,419. Although the applicant submitted data that related to the estimated cost of the Zilver® PTX®, the applicant noted that the cost of the technology was proprietary information. Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $54,547 (all calculations above were performed using unrounded numbers). Because the final inflated case-weighted average standardized charge per case for the applicable MS–DRGs exceeded the case-weighted threshold amount, the applicant maintained that the Zilver® PTX® would meet the cost criterion.

The applicant used the same methodology above to demonstrate that it meets the cost criterion with the only difference being that it included cases that used one or two bare metal stents instead of just one bare metal stent. Using this methodology, the applicant determined a final inflated case-weighted average standardized charge per case of $62,455. Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $54,474 (all calculations above were performed using unrounded numbers). Because the final inflated case-weighted average standardized charge per case for the applicable MS–DRGs exceeded the case-weighted threshold amount, the applicant maintained that the Zilver® PTX® would meet the cost criterion.

We are inviting public comments on whether or not the Zilver® PTX® meets the cost criterion. In addition, we are inviting public comments on the methodologies used by the applicant in its analysis, including its assumptions regarding the types of cases in which this technology could potentially be used and the number of stents required for each case.

In an effort to demonstrate that the technology meets the substantial clinical improvement criterion, the applicant shared several findings from the clinical trial data. The applicant stated that current treatment options for patients who have been diagnosed with PAD includes angioplasty, bare metal stenting, bypass graft, and endarterectomy. The applicant asserted that the Zilver® PTX® meets the substantial clinical improvement criterion because it decreases the

[6] Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S. (2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. Circulation Cardiovascular Interventions, published online September 27, 2011, 495–504.

recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations.

The applicant cited a 479-patient, multicenter, multinational randomized controlled trial that compared the Zilver® PTX® to balloon angioplasty [7]; an additional component of the study allowed a direct comparison of the Zilver® PTX® to a bare (uncoated) metal Zilver® stent. Patients were randomized to treatment with the Zilver® PTX® stent (treatment group) or with PTA (control group). Recognizing that balloon angioplasty may not be successful acutely, the trial design mandated provisional stent placement immediately after failure of balloon angioplasty in instances of acute PTA failure. Therefore, patients with suboptimal (failed) PTA underwent a secondary randomization to stenting with either Zilver® PTX® or bare Zilver stents. This secondary randomization allows evaluation of the Zilver® PTX® stent compared to a bare metal stent. The primary safety endpoint of the randomized controlled study was ''Event-Free Survival'' (EFS), defined as ''freedom from the major adverse events of death, target lesion revascularization, target limb ischemia requiring surgical intervention or surgical repair of the target vessel, and freedom of worsening systems as described by the Rutherford classification by 2 classes or to class 5 or 6.'' The primary effectiveness endpoint was primary patency (defined as a less than 50 percent re-narrowing). We note that we are concerned that other endpoints such as walking, walking speed, and climbing were not considered as primary endpoints to demonstrate the effectiveness of the Zilver® PTX®.

According to the applicant, the Zilver® PTX® had an EFS of 90.4 percent compared to balloon angioplasty, which had an EFS of 83.9 percent, at 12 months demonstrating that the Zilver® PTX® is as safe or safer than balloon angioplasty. The applicant further stated that this benefit was maintained at 24 months. In addition, the applicant noted that the Zilver® PTX® demonstrated a 50-percent reduction in restenosis rates compared to angioplasty and a 20-percent reduction compared to bare metal stents. The 12-month patency rate for the Zilver® PTX® was 82.7 percent, which compared favorably to the balloon angioplasty patency rate of 32.7 percent. In the provisional stenting arm of the study, which allowed a direct comparison of the Zilver® PTX® and a bare metal stent, the Zilver® PTX® primary patency exceeded the bare metal stent patency by nearly 20 percent (87.3 percent versus 72.3 percent at 12 months). The applicant stated that these differences are significant, as they result in a substantial clinical improvement compared to angioplasty and bare metal stenting, with patients being spared a recurrence of their leg pain and the need to be admitted to the hospital for repeat procedures on these treated lesions. The applicant also submitted 3 years of follow-up data, which the applicant maintained support that the Zilver® PTX® is more effective in maintaining primary patency.[8]

The applicant also cited a prospective, multicenter, multinational, 787-patient single arm study on the Zilver® PTX® that demonstrated similar safety and effectiveness results consistent with those from the pivotal randomized controlled study above. The applicant cited an EFS for the Zilver® PTX® of 89.0 percent and an 86.2 percent primary patency rate. According to the applicant, these results confirm the safety and effectiveness of the Zilver® PTX®, and compare favorably to current results for angioplasty and bare metal stenting. The applicant further stated that these results also demonstrate a 67 to 81 percent relative reduction in Target Lesion Revascularization (the need to retreat an already treated lesion that has restenosed, resulting in a recurrence of symptoms) rates compared to recently published results of contemporary bare metal stents.[9]

We also are concerned that on April 24, 2013, the FDA announced that, based on its investigation into a small number of complaints that the delivery system of the device had separated at the tip of the inner catheter, Cook Medical has initiated a nationwide/global voluntary recall of its Zilver® PTX® Drug Eluting Peripheral Stent. We refer readers to *http://www.fda.gov/Safety/Recalls/ucm349421.htm?source=govdelivery* for more information regarding this announcement.

We are inviting public comments regarding whether the Zilver® PTX® meets the substantial clinical improvement criterion. We note that we did not receive any public comments on the Zilver® PTX® during the new technology town hall meeting's public comment period.

e. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2014. The MitraClip® System is a transcatheter mitral valve 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 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 mitral valve as the heart contracts. If the amount of blood that leaks back into the mitral valve is minimal then intervention is usually not necessary. However, if the amount of blood 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 mitral regurgitation can lead to heart failure and death. The American College of Cardiology (ACC) and the American Heart Association (AHA) issued practice guidelines in 2006 recommending intervention for moderate-severe or severe MR (3+ to 4+). The applicant stated that the MitraClip® System is intended ''for patients with symptomatic, significant mitral regurgitation who have been determined by a cardiac surgeon to be too high risk for open mitral valve surgery and in whom existing co-morbidities would not preclude the expected benefit from correction of the mitral regurgitation.''

The MitraClip® System performs percutaneous mitral valve repair. The applicant noted that the MitraClip® 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

[7] Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S. (2011), Paclitaxeleluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. Circulation Cardiovascular Interventions, published online September 27, 2011, 495–504.

[8] Dake, MD., VIVA 2012, October 10, 2012; Las Vegas, Nevada.

[9] Dake, M. D., Scheinert, D., Tepe, G., Tessarek, J., Fanelli, F., Bosiers, M., et al., (2011). Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. *Journal of Endovascular Therapy, 18*(5), 613–623.

of MR since the early 1990s.[10 11 12 13 14] 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 coaptation (''approximation'') of the two leaflets. As a result, when the suture is placed in the middle of the valve, the valve will have a functional double orifice during diastole, thus the alternate name for the procedure ''Double Orifice Repair.''

With regard to the newness criterion, the manufacturer submitted a Premarket Approval (PMA) application in support of obtaining FDA approval for the MitraClip® System. 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® technology. On March 20, 2013, a meeting was held by the Circulatory System Devices Panel of the Medical Devices Advisory Committee of the FDA to discuss, make recommendations, and vote on information related to the PMA application for the MitraClip® System. Specifically, the Committee was charged with determining if the data presented by the applicant demonstrated a reasonable assurance of safety and effectiveness. We refer readers to the following FDA Web site for additional detailed information and meeting materials regarding the MitraClip® System *http://www.fda.gov/AdvisoryCommittees/Calendar/ucm339809.htm*. In addition, a summary of the March 20, 2013 meeting can be located on the following FDA Web site *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM345235.pdf*. We are inviting public comments regarding how the MitraClip® System meets the newness criterion.

With regard to the cost criterion, the applicant conducted four separate analyses. The applicant noted that while ICD–9–CM procedure code 35.97 groups to MS–DRGs 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with Major Complication or Comorbidity (MCC) or 4+ Vessels/Stents), 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC), 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC), 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC), and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC), clinical experience with the MitraClip® has demonstrated that it is extremely rare for a patient to receive stents concurrently with the MitraClip® procedure. The applicant further cited the FY 2013 IPPS/LTCH PPS final rule (77 FR 55308) which stated, ''According to the Food and Drug Administration's (FDA's) terms of the clinical trial for MitraClip™, the device is to be implanted in patients without any additional surgeries performed. Therefore, based on these terms, we stated that while the procedure code is assigned to MS–DRGs 246 through 251, the most likely MS–DRG assignments would be MS–DRGs 250 and 251.'' As a result, the applicant stated that it conducted its analyses solely for MS–DRGs 250 and 251 to demonstrate that the cases involving MitraClip® meet the incremental cost thresholds provided in Table 10 for those MS–DRGs.

The applicant included two analyses that utilize the FY 2011 MedPAR file and two analyses of hospital UB–04 claims data from the EVEREST II Continued Access Study that were collected during FY 2012. Below is a summary of the applicant's four data analyses, including the methodology and the findings for each.

- *Analysis 1:* The applicant searched the FY 2011 MedPAR file for cases reporting procedure code 35.97 that mapped to MS–DRGs 250 and 251. According to the applicant, this search yielded actual MitraClip® procedures that were performed in an IDE study setting where hospitals obtained the MitraClip® System at a reduced investigational price; the applicant stated that it is likely that hospitals did not bill at all for the investigational device or submitted billed charges that were significantly less than the actual device acquisition costs (we refer readers to the explanation below). The applicant found 39 cases in MS–DRG 250 (29 percent of all cases), and 94 cases in MS–DRG 251 (71 percent of all cases), which resulted in a case-weighted average charge per case of $97,918. The applicant then standardized the charges using the FY 2011 final rule impact file and inflated the standardized charges using two different inflation factors. The first approach used a factor of 4.6 percent, which was based on data from the U.S. Department of Labor's Bureau of Labor Statistics non-seasonally adjusted Consumer Price Index for All Urban Consumers between January 2011 and January 2013. This resulted in an inflated case-weighted average standardized charge per case of $79,346. The second approach used a factor of 18.6 percent based on the growth in charges between 2009 and 2011 in MS–DRGs 250 and 251 and adjusting for case-mix year over year. This resulted in an inflated case-weighted average standardized charge per case of $89,986. The applicant noted that both approaches used to determine the inflated case-weighted average standardized charge per case were calculated without any adjustments to reflect the reduced investigational price or inadequate hospital billing.

In order to determine if hospitals adequately billed for the device, the applicant analyzed the cost of the device on each claim by summing the charges that map to the 15 CMS IPPS cost centers (77 FR 53340). The applicant then calculated the standardized cost for this subset of charges by multiplying the standardized charges in each cost center by the CMS national CCR for each cost center in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53340). The applicant asserted that, whereas all hospitals in the study were charged a uniform investigational price for the MitraClip® System, this analysis confirmed that some hospitals did not bill at all for the device or charged substantially less than the actual hospital acquisition cost, which is likely due to the investigational status of the technology. The applicant explained that the mean total standardized costs in the ''Supplies and Equipment'' cost center in the FY 2011 MedPAR file for MitraClip® cases were remarkably low for MS–DRGs 250 and 251, respectively. According to the applicant, the mean total standardized costs in the ''Supplies and Equipment'' cost center reflect only 50 percent of the actual MitraClip® System costs not inclusive of other supply and equipment costs associated with the MitraClip® procedure and hospital stay. Therefore, the applicant

[10] Maisano, F., et al., The double-orifice technique as a standardized approach to treat mitral regurgitation due to severe myxomatous disease: surgical technique, Eur J Cardiothorac Surg, 2000, 17(3): p. 201–5.

[11] Maisano, F., et al., The edge-to-edge technique: a simplified method to correct mitral insufficiency, Eur J Cardiothorac Surg, 1998, 13(3): p. 240–5; discussion 245–6.

[12] Totaro, P., et al., Mitral valve repair for isolated prolapse of the anterior leaflet: an 11-year follow-up, Eur J Cardiothorac Surg, 1999, 15(2): p. 119–26.

[13] Umana, J.P., et al., ''Bow-tie'' mitral valve repair: an adjuvant technique for ischemic mitral regurgitation, Ann Thorac Surg, 1998, 66(5): p. 1640–6.

[14] Alfieri, O. and F. Maisano, An effective technique to correct anterior mitral leaflet prolapse, J Card Surg, 1999, 14(6): p. 468–70.

believed that Analysis 1 severely underestimated the actual hospital costs.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 250 and 251 was $63,097 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS–DRGs for both approaches discussed above exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip® System would meet the cost criterion.

• *Analysis 2:* The second analysis is identical to the first analysis (the applicant searched the FY 2011 MedPAR file for cases reporting procedure code 35.97 that mapped to MS–DRGs 250 and 251) except that the applicant excluded hospital claims that either did not include any charge for the device-dependent procedure or included a charge that was significantly less than the actual device acquisition cost. The applicant believed that these exclusions would provide more accurate data on the costs associated with the MitraClip® procedure in the IDE study when hospitals obtained the MitraClip® System at a reduced investigational price. The applicant explained that it included only those cases where the standardized charge for the ''Supplies and Equipment'' cost center, reduced by each hospital's average hospital-wide CCR (rather than using CMS national CCRs for each cost center), was greater than $10,000, which is lower than the acquisition cost for the MitraClip® System. The applicant stated that this analysis reflects a conservative but more appropriate estimate of the actual costs incurred by the hospitals during the clinical trial than the first analysis.

Using the methodology above, the applicant found 12 cases in MS–DRG 250 (22 percent of all cases) and 43 cases in MS–DRG 251 (78 percent of all cases), which resulted in a case-weighted average charge per case of $112,434. The applicant then standardized the charges using the FY 2011 final rule impact file and inflated the standardized charges using two different inflation factors. The first approach used a factor of 4.6 percent, which was based on data from the U.S. Department of Labor's Bureau of Labor Statistics non-seasonally adjusted Consumer Price Index for All Urban Consumers between January 2011 and January 2013. This resulted in an inflated case-weighted average standardized charge per case of $97,289. The second approach used a factor of 18.6 percent based on the growth in charges between 2009 and 2011 in MS–DRGs 250 and 251 and adjusting for case-mix year over year. This resulted in an inflated case-weighted average standardized charge per case of $110,335.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 250 and 251 was $61,896 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS–DRGs for both charge inflation approaches discussed above exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip® System would meet the cost criterion.

• *Analysis 3:* Because the first two analyses sought only to estimate standardized charges for the MitraClip® procedure in an investigational setting with a reduced price for the device, the applicant submitted two additional analyses using hospital charges in a commercial setting and a commercial device price. Rather than using MedPAR data, the applicant utilized hospital UB–04 claims collected from the ongoing EVEREST II Continued Access Study in addition to claims from compassionate-use cases. The applicant stated that patient characteristics and charges for both of these cases were not significantly different.

The applicant analyzed 98 claims from 21 sites (for discharges on or after October 1, 2011 through discharges on or before September 30, 2012 (FY 2012 claims data)) and excluded 18 cases because the cases either did not map to MS–DRGs 250 or 251, or the patient was below the age of 65 years. Of these remaining 80 cases, 17 mapped to MS–DRG 250 (21.3 percent of all cases) and 63 mapped to MS–DRG 251 (78.8 percent of all cases), which resulted in a case-weighted average charge per case of $112,509. The case-weighted average charge per case above includes clinical trial charges related to the MitraClip® System, which does not reflect the full commercial charge for the MitraClip® System. Therefore, the applicant removed the amount of clinical trial charges related to the MitraClip® System. The applicant then standardized the charges using the FY 2012 final rule impact file and inflated the standardized charges using the two different approaches described in the first and second analyses (an inflation factor of 4.6 percent and 18.6 percent, respectively).

The applicant then added commercial charges for the device to the inflated standardized charges (for both charge inflation approaches). Although the applicant submitted data that related to the estimated cost of the MitraClip® System, the applicant noted that the cost of the technology was proprietary information. To compute the commercial charges for the MitraClip® System, the applicant took the European commercial price of the MitraClip® System, converted the cost to U.S. dollars by multiplying the amount by an exchange rate of 1.38, and then divided the result by the ''Supplies and Equipment'' cost center CCR (in the FY 2013 IPPS/LTCH PPS final rule) of 0.335. This resulted in an inflated case-weighted average standardized charge per case of $129,019 and $132,372 under the first and second charge inflation approaches, respectively.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 250 and 251 was $61,805 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS–DRGs for both charge inflation approaches exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip® System would meet the cost criterion.

• *Analysis 4:* The fourth analysis was similar to the third analysis. However, instead of basing commercial charges on the European commercial price, the applicant used the anticipated U.S. commercial price to determine the commercial charges for the device. Similar to above, the applicant determined a case-weighted average charge per case of $112,509. The applicant then removed the clinical trial charges related to the MitraClip® System (for each claim), standardized the charges using the FY 2012 final rule impact file, and inflated the standardized charges using both charge inflation approaches discussed above.

The applicant then added commercial charges for the device to the inflated standardized charges (for both charge inflation approaches). As mentioned above, although the applicant submitted data that related to the estimated cost of the MitraClip® System, the applicant noted that the cost of the technology was proprietary information. To compute the commercial charges for the MitraClip® System, the applicant used the anticipated U.S. commercial price of the MitraClip® System and divided the amount by the ''Supplies and Equipment'' cost center CCR (in the FY 2013 IPPS/LTCH PPS final rule) of 0.335. This resulted in an inflated case-weighted average standardized charge per case of $136,183 and $139,535

under the first and second charge inflation approaches, respectively.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS–DRGs 250 and 251 was $61,805 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS–DRGs for both charge inflation approaches exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip® System would meet the cost criterion.

We are inviting public comments on whether or not the MitraClip® System meets the cost criterion. In addition, we are inviting public comments on the methodologies used by the applicant in its four analyses.

The applicant asserted that the MitraClip® System meets the substantial clinical improvement criterion. The applicant explained that studies have indicated that a significant proportion of patients are not eligible for mitral valve repair and/or replacement surgery because of risk factors including reduced left ventricular function, significant comorbidities, and advanced age. As a result, the applicant stated that there is a significant unmet clinical need for patients with severe MR who are too high risk for surgery and receiving palliative medical management.

The applicant further stated that although many of the patients who are refused surgery die in the intervening months to years, the economic burden to the healthcare system of mitral regurgitation in elderly patients not deemed suitable for conventional open chest surgery is considerable. The applicant noted that the vast majority of such patients are repeatedly hospitalized, often with prolonged lengths of in-hospital stays, and, even when returned to the community, they consume additional resources from the primary care and social services. The applicant asserted that the quality of life enjoyed by these patients is also poor and their mortality rates are high. The applicant cited the 2012 European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) clinical practice guideline for valvular heart disease, which recommended that the MitraClip® procedure be considered in high surgical risk patients with symptomatic severe secondary MR.

The applicant also stated that it would meet the substantial clinical improvement criterion based on clinical studies that have consistently shown that the MitraClip® procedure leads to a significant reduction of MR, improvements in left ventricular (LV) function including LV volumes and dimensions, improved patient outcomes as measured by improvements in New York Heart Association (NYHA) functional class, health-related quality of life and reductions in heart-failure related hospitalizations, and significantly lower mortality than predicted surgical mortality.

The applicant cited clinical data from the EVEREST II High Risk Study [15] and from the EVEREST II Continued Access Study/Registry (REALISIM) [16]. The applicant also cited clinical data from a high risk cohort of patients (EVEREST II High Risk Cohort), which is an integrated analysis of the following: (1) Patients within the EVEREST II High Risk Study who met eligibility criteria for being too high risk to undergo mitral valve surgery; and (2) patients within the EVEREST II Continued Access Study/Registry who were too high risk for surgery using identical eligibility inclusion criteria.

In addition to the published clinical experience from the EVEREST studies, the applicant cited data on the use of the MitraClip® device in a ''real-world'' setting published recently by a select number of European centers as part of their individual and/or multi-center commercial experience or enrollment in the MitraClip® device group of the ACCESS–EU post-approval clinical trial in Europe. The European use of the MitraClip® device is focused on patients who are too high risk for surgery and patients are selected for therapy using a multi-disciplinary ''heart team'' approach.

The applicant stated that published reports of the MitraClip® procedure have consistently demonstrated a significant reduction in MR that is durable out to 1, 2, and 3 years. The applicant cited the EVEREST II High Risk Study, which demonstrated that the MitraClip® procedure successfully reduced MR for high-risk patients with results durable out to 2 years. The applicant also noted that the proportion of patients with significant MR (MR grade ≥3+) was reduced from 99 percent at baseline to 22 percent at 1 year follow-up ($p<0.0001$). The applicant further noted that reduction of MR was also associated with significant improvements in left ventricular dimensions including LV end diastolic and systolic volumes ($p<0.0001$) consistent with positive ventricular remodeling.

According to the applicant, the most recent available data from the EVEREST II High Risk Cohort submitted to the FDA for high-risk patients demonstrated a significant reduction in severe MR from 86 percent at baseline to 13 percent at 2 years ($p<0.0001$), improvements in LV dimensions and volumes sustained at 2 years, and a 48-percent reduction in rates of heart failure-related hospitalizations between the baseline and the 12-month follow-up period after the MitraClip® procedure ($p<0.0001$).

The applicant noted that patients treated with MitraClip® reported substantial clinical improvements in NYHA functional class from baseline at both 1 and 2 year followup. The applicant explained that the NYHA classification system assigns patients into one of four categories representing the extent of heart failure based on how much they are limited during physical activity. In the EVEREST II High-Risk Cohort, the applicant stated that the proportion of patients with NYHA class III/IV representing marked or severe limitations in activity was significantly reduced from 82 percent at baseline to 17 percent at 1 year ($p<0.0001$). The applicant noted that these results also have been consistently shown in multiple other published studies.

Based on data from the EVEREST II High Risk Cohort, the applicant cited additional data demonstrating that the MitraClip® treatment is associated with clinically and statistically significant improvements in general health-related quality of life. The applicant explained that the RAND SF–36 health survey, a quality of life instrument, demonstrated similar physical and mental component scores after 30 days and 1 year. In addition, the applicant stated that the MitraClip® is associated with lower than predicted mortality rates at 30 days as measured by the Society for Thoracic Surgery (STS) Mortality Risk Score. Also, mortality at 1 year is favorable when (1) comparing the MitraClip® to published literature [17 18 19 20 21 22 23] and

[15] Whitlow et al., Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair: The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. JACC 2012;59:130–139.

[16] Feldman et al., Percutaneous Repair or Surgery for Mitral Regurgitation. NEJM 2011;364:1395–1406.

[17] Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? Eur Heart J. 2007 Jun;28(11):1358–65.

[18] Patel JB, Borgeson DD, Barnes ME, Rihal CS, Daly RC, Redfield MM.: Mitral regurgitation in patients with advanced systolic heart failure. J Card Fail. 2004 Aug;10(4):285–91.

[19] Trichon BH, Felker GM, Shaw LK, Cabell CH, O'Connor CM: Relation of frequency and severity of mitral regurgitation to survival among patients with left ventricular systolic dysfunction and heart failure, Am J Cardiol. 2003 Mar 1. 91(5):538–43.

(2) comparing MitraClip® mortality to a high-risk concurrent control group of patients treated with medical management.

In conclusion, the applicant cited data from the ACCESS–EU study as presented at the European Society of Cardiology Congress in August 2012, which demonstrated improvement in disease-specific quality of life measures including the Minnesota Living with Heart Failure Questionnaire and Six Minute Walk Test.

We note that, similar to the FDA, as referenced above, we are concerned that the applicant performed post hoc analyses on a different patient population and revised the initial indication for use for the MitraClip® after learning that the FDA expressed concern regarding the PMA based on insufficient data resulting from the initial indication for use and patient population in the EVEREST II RCT. As we discuss below, data results from 2 years of the EVEREST II RCT also demonstrated that surgery reduced mitral regurgitation more than the percutaneous MitraClip® System. However, both the surgical patients and the MitraClip® patients showed comparable results for improved left ventricular function, NYHA functional class, and quality of life. Subsequent to this trial, the applicant conducted a retrospective review of registry data to support the revised indication for use. This retrospective analysis involved pooling two registry data sets (the EVEREST II High Risk Registry (HRR) and the REALISM HRR Continued Access Protocol (CAP)) in a post hoc manner, which resulted in major design flaws and data interpretation limitations. The pooled registry data sets were referred to as the Integrated High Surgical Risk Cohort.

We note that, the EVEREST II HRR and the REALISM HRR CAP were not intended to be used as pivotal data sets. The applicant was previously informed by the FDA that without positive pivotal trial results, the PMA application could not be approved based on the data results of the EVEREST II RCT by itself. Therefore, the FDA suggested the additional studies (the EVEREST II HRR and the REALISM HRR CAP) to complement the randomized study and, therefore, could be considered adjunctive to the EVEREST II RCT.

In our review of the clinical trials' data, we agree with the FDA regarding the following key points:

- Post hoc analyses of pooled data sets retain all of the individual shortcomings of the individual data sets;
- Pooling does not enhance the utility and scientific value of uncontrolled single arm registries with no comparators; and
- Inappropriate pooling introduces additional confounders.

It is also unclear what the appropriate target population for the MitraClip® System is because clinical trials conducted by the applicant included patients with both functional and degenerative mitral regurgitation, which makes it difficult to determine which group of patients may benefit more or less from the technology. For example, in a subgroup analysis of the EVEREST II RCT, authors concluded that older patients and those patients with functional mitral regurgitation or abnormal left ventricular function had results more comparable to surgical repair. Data results from 2 years of the EVEREST II RCT also demonstrated that surgery reduced mitral regurgitation more than the percutaneous MitraClip® System. However, both the surgical patients and the MitraClip® System's patients showed comparable results for improved left ventricular function, NYHA functional class, and quality of life.

We are inviting public comments on whether this technology meets the substantial clinical improvement criterion, particularly in comparison to other surgical therapies such as mitral valve repair or replacement, and also with regard to the appropriate target population for this technology.

We received nine comments on the MitraClip® System during the town hall meeting's public comment period. These comments are summarized below.

Comment: Several commenters expressed support for new technology add-on payments for the MitraClip® System and recommended that the technology be reassigned from MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with and without MCC, respectively) to MS–DRGs 216, 217, 218, 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedure with and without Cardiac Catheterization with MCC, CC, and without CC/MCC, respectively).

Response: We appreciate the commenters' support. However, we note that we did not request public comments nor propose to make any changes to the MS–DRG classification for the MitraClip® System. Because these comments are outside the scope of the new technology add-on payment application included in this proposed rule, we are not providing a complete summary of and response to these comments. We encourage the commenters to review the process for submitting comments regarding MS–DRG classifications as outlined in section II.G. of the preamble of this proposed rule.

Comment: Several commenters stated that they supported the application for new technology add-on payments for the MitraClip® System because it is a novel technology utilizing the transcatheter approach to repair the mitral valve and has demonstrated substantial clinical improvement. According to the commenters, the technology is intended to be used for high-risk patients who do not have other treatment options available due to the severity of their mitral regurgitation and other comorbidities, such as heart failure. The commenters noted that the percutaneous MitraClip® System results in significant improvement in quality of life for this group of patients for whom conventional surgery is contraindicated.

One commenter stated that another benefit of the MitraClip® System is that it offers patients with all forms of mitral regurgitation the opportunity to receive treatment much earlier, thereby resulting in improved cardiac function, reduced heart failure, and increased savings to the healthcare system.

Another commenter expressed support for the MitraClip® System and noted that surgery for this high-risk patient population is not a viable alternative and neither are the currently available medical therapy options, as evidenced by the readmission rates for congestive heart failure exacerbations in this group of patients. This commenter also noted that the MitraClip® device has proven to reduce the degree of mitral regurgitation as shown in a number of high-risk patient registries and clinical trials. The commenter further noted that savings could be realized with the reductions in readmissions for heart failure exacerbations for this group of patients.

[20] Bursi F, Enriquez-Sarano M, Nkomo VT, Jacobsen SJ, Weston SA, Meverden RA, Roger VL: Heart failure and death after myocardial infarction in the community: the emerging role of mitral regurgitation. Circulation. 2005 Jan 25;111(3):295–301.34.

[21] Grigioni F, Enriquez-Sarano M, Zehr KJ, Bailey KR, Tajik AJ: Ischemic mitral regurgitation: long-term outcome and prognostic implications with quantitative Doppler assessment. Circulation. 2001 Apr 3;103(13):1759–64.

[22] Koelling TM, Aaronson KD, Cody RJ, Bach DS, Armstrong WF: Prognostic significance of mitral regurgitation and tricuspid regurgitation in patients with left ventricular systolic dysfunction, Am Heart J. 2002 Sep;144(3):524–9.

[23] Cioffi G, Tarantini L, De Feo S, Pulignano G, Del Sindaco D, Stefenelli C, Di Lenarda A, Opasich C.: Functional mitral regurgitation predicts 1-year mortality in elderly patients with systolic chronic heart failure. Eur J Heart Fail. 2005 Dec;7(7):1112–7.

One commenter indicated that the MitraClip® System meets the substantial clinical improvement criterion because it offers nonoperative patients a device that could ''potentially revolutionize management of nonsurgical patients with severe mitral regurgitation.'' Another commenter stated that the MitraClip® System ''represents a landmark in our ability to perform mitral valve surgeries with less risk.'' This commenter further stated that the ''MitraClip® joins TAVR (Transcatheter aortic valve replacement) and TPVI (Transcatheter pulmonary valve implantation) as new percutaneous surgical therapies for patients with valvular heart disease who are not candidates for traditional valve replacement or repair.''

Another commenter noted that the MitraClip® System has shown substantial clinical improvement in patients considered too high risk for surgery as demonstrated by the EVEREST II cohort, including improvement in patients NYHA functional class, reduced hospitalizations, and improved left ventricular function.

Response: We appreciate the commenters' support. We have considered these comments received during the town hall meeting's public comment period in this proposed rule. As stated above, we are inviting additional public comments on whether the MitraClip® System meets the substantial clinical improvement criterion, particularly in comparison to other surgical therapies such as mitral valve repair or replacement, and also with regard to the appropriate target population for this technology.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts ''for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.'' We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2014 hospital wage index based on the statistical areas appears under section III.B. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2014 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed below in section III.H. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2014 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply beginning October 1, 2013 (the FY 2014 wage index) appears under section III.F. of the preamble of this proposed rule.

B. Core-Based Statistical Areas for the Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we define hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by OMB. The current statistical areas are based on OMB standards published on December 27, 2000 (65 FR 82228) and Census 2000 data and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02). For a discussion of OMB's delineations of CBSAs and our implementation of the CBSA definitions, we refer readers to the preamble of the FY 2005 IPPS final rule (69 FR 49026 through 49032). We also discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53365) that, in 2013, OMB plans to announce new area delineations based on new standards adopted in 2010 (75 FR 37246) and the 2010 Census of Population and Housing data. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provides guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data.''

In order to implement these changes for the IPPS, it is necessary to identify the new area designation for each county and hospital in the country. While the revisions OMB published on February 28, 2013 are not as sweeping as the changes OMB announced in 2003, the February 28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that have been split apart. In addition, the effect of the new designations on various hospital reclassifications, the outmigration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) provided for under section 1886(d)(8)(B) of the Act must be considered. These are just a few of the many issues that need to be considereed regarding the effects of the new designations prior to proposing and establishing policies.

However, because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications must be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of this FY 2014 proposed rule. By the time the bulletin was issued, the FY 2014 IPPS proposed rule was in the advanced stages of development. We had already developed the FY 2014 proposed wage index based on the previous OMB definitions. We note that, in June 2003,

OMB announced changes resulting from the 2000 Census, and at that time, CMS proposed and implemented the changes during the following year's rulemaking cycle for FY 2005. Although OMB published the data earlier than June this year, we still are in essentially the same situation as we were in 2003 because the data are not available in time to be incorporated into this year's rulemaking cycle. To allow for sufficient time to assess the new changes and their ramifications, we intend to propose changes to the wage index based on the newest CBSA changes in the FY 2015 proposed rule. We refer readers to the FY 2005 IPPS final rule (69 FR 49026 through 49034) for those interested in learning about the issues we may need to address next year in proposing to implement the latest OMB update for FY 2015, and some of the policy decisions that we may consider making.

C. Worksheet S–3 Wage Data for the Proposed FY 2014 Wage Index

The proposed FY 2014 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2010 (the FY 2013 wage indices were based on data from cost reporting periods beginning during FY 2009).

1. Included Categories of Costs

The proposed FY 2014 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 2013, the proposed wage index for FY 2014 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2014 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 Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index are also currently used to calculate wage indices applicable to other providers, such as SNFs, home health agencies (HHAs), 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 indices for non-IPPS providers, other than for LTCHs. Such comments should be made in response to separate proposed rules for those providers.

D. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2014 wage index were obtained from Worksheet S–3 of the Medicare cost report for cost reporting periods beginning on or after October 1, 2009, and before October 1, 2010. For wage index purposes, we refer to cost reports during this period as the ''FY 2010 cost report,'' the ''FY 2010 wage data,'' or the ''FY 2010 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 36, Sections 3605.2 and 3605.3 for Form CMS–2552–96 and Chapter 40, Sections 4005.2 through 4005.4 for Form CMS–2552–10. Hospitals with cost reporting periods beginning on or after October 1, 2009 and before May 1, 2010 reported FY 2010 data on Form CMS–2552–96. Hospitals with cost reporting periods beginning on or after May 1, 2010 and before October 1, 2010 reported FY 2010 data on the new Form CMS–2552–10. The data file used to construct the wage index includes FY 2010 data submitted to us as of March 1, 2013. 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 fiscal intermediaries/MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2014 wage index, we identified and excluded 44 providers with data that were too aberrant to include in the proposed wage index, although if data elements for some of these providers are corrected, we intend to include some of these providers in the final FY 2014 wage index. We instructed fiscal intermediaries/MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 10, 2013. We intend that all unresolved data elements will be resolved by the date the FY 2014 final rule is issued. The revised data will be reflected in the FY 2014 IPPS final rule.

In constructing the proposed FY 2014 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2010, 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 this proposed rule, we removed 4 hospitals that converted to CAH status on or after February 14, 2012, the cut-off date for CAH exclusion from the FY 2013 wage index, and through and including February 14, 2013, the cut-off date for CAH exclusion from the FY 2014 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2014 wage index is calculated based on 3,427 hospitals.

For the proposed FY 2014 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 2013 wage index (77 FR 53366). Table 2 containing the proposed FY 2014 wage index associated with this proposed rule (available on the CMS Web site) includes separate wage data for the campuses of six multicampus hospitals (two additional multicampus hospitals have been added to the wage index calculation for FY 2014).

E. Method for Computing the Proposed FY 2014 Unadjusted Wage Index

The method used to compute the proposed FY 2014 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012 final wage index without an occupational mix adjustment (76 FR 51591 through 51593) and which we discussed and used for the FY 2013 final wage index without an occupational mix adjustment (77 FR 53366 through 53367).

As discussed in the FY 2012 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, 2009, through April 15, 2011, for private industry hospital workers from the BLS' Compensation and Working Conditions. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage for FY 2014. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2009	11/15/2009	1.02682
11/14/2009	12/15/2009	1.02490
12/14/2009	01/15/2010	1.02299
01/14/2010	02/15/2010	1.02116
02/14/2010	03/15/2010	1.01941
03/14/2010	04/15/2010	1.01768
04/14/2010	05/15/2010	1.01591
05/14/2010	06/15/2010	1.01412
06/14/2010	07/15/2010	1.01235
07/14/2010	08/15/2010	1.01064
08/14/2010	09/15/2010	1.00898
09/14/2010	10/15/2010	1.00738
10/14/2010	11/15/2010	1.00584
11/14/2010	12/15/2010	1.00434
12/14/2010	01/15/2011	1.00288
01/14/2011	02/15/2011	1.00143
02/14/2011	03/15/2011	1.00000
03/14/2011	04/15/2011	0.99860

For example, the midpoint of a cost reporting period beginning January 1, 2010, and ending December 31, 2010, is June 30, 2010. An adjustment factor of 1.01235 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as described above and in the FY 2013 IPPS/LTCH PPS final rule, the proposed FY 2014 national average hourly wage (unadjusted for occupational mix) is $38.2384. The proposed FY 2014 Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $16.4873.

F. Proposed Occupational Mix Adjustment to the Proposed FY 2014 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 Proposed FY 2014 Occupational Mix Adjustment Based on the 2010 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 2013 IPPS/LTCH PPS final rule (77 FR 53367 through 53368), the occupational mix adjustment to the FY 2013 wage index was based on data collected on the 2010 Medicare Wage Index Occupational Mix Survey (Form CMS–10079 (2010)). For the FY 2014 wage index, we are proposing to again use occupational mix data collected on the 2010 survey to compute the occupational mix adjustment for FY 2014. We are including data for 3,188 hospitals that also have wage data included in the proposed FY 2014 wage index.

2. New 2013 Occupational Mix Survey for the FY 2016 Wage Index

As stated earlier, 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 used occupational mix data collected on the 2010 survey to compute the occupational mix adjustment for FY 2013 and the proposed FY 2014 wage index associated with this proposed rule. We also plan to use the 2010 survey data for the FY 2015 wage index. Therefore, a new measurement of occupational mix will be required for FY 2016.

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 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). This survey is pending OMB review, and is available on the CMS Web site at: *http://www.cms.hhs.gov/PaperworkReductionActof1995* by clicking on ''PRA Listings.'' (The OMB control number for this collection of information is 0938–0907.) Hospitals are required to submit their completed 2013 surveys to their fiscal intermediaries/MACs by July 1, 2014. The preliminary, unaudited 2013 survey data will be released afterward, along with the FY 2012 Worksheet S–3 wage data, for the FY 2016 wage index review and correction process.

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2014

For FY 2014, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012 and FY 2013 wage indices (76 FR 51582 through 51586, and 77 FR 53367 through 53368, respectively). As a result of applying this methodology, the proposed FY 2014 occupational mix adjusted national average hourly wage is $38.2094. The proposed FY 2014 occupational mix adjusted Puerto Rico-specific average hourly wage is $16.5300.

Because the occupational mix adjustment is required by statute, 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 proposed FY 2014 wage index. For the FY 2010 survey, the response rate was 91.7 percent. In the proposed FY 2014 wage index established in this proposed 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 beginning with the 2010 occupational mix survey. We instructed fiscal intermediaries/MACs to continue gathering this information as part of the FY 2014 wage index desk review process. We will review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2014 Occupational Mix Adjusted Wage Index

1. Analysis of the Proposed Occupational Mix Adjustment and the Proposed Occupational Mix Adjusted Wage Index

As discussed in section III.F. of this preamble, for FY 2014, we are proposing to apply the proposed occupational mix adjustment to 100 percent of the proposed FY 2014 wage index. We calculated the proposed occupational mix adjustment using data from the 2010 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 proposed FY 2014 wage index results in a proposed national average hourly wage of $38.2094 and a proposed Puerto-Rico specific average hourly wage of $16.5300. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2010 Worksheet S–3, Parts II and III, cost report data for use in calculating the proposed FY 2014 wage index, we calculated the proposed FY 2014 wage index using the occupational mix survey data from 3,188 hospitals. Using the Worksheet S–3, Parts II and III, cost report data of 3,427 hospitals and occupational mix survey data from 3,188 hospitals represents a 93.0 percent survey response rate. The proposed FY 2014 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	Proposed average hourly wage
National RN	37.432120148
National LPN and Surgical Technician	21.773706724
National Nurse Aide, Orderly, and Attendant	15.327583858
National Medical Assistant	17.213605923
National Nurse Category	31.811167234

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $31.811167234. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2010 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 43.44 percent, and the national percentage of hospital employees in the all other occupations category is 56.56 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 21.9 percent in one CBSA, to a high of 62.0 percent in another CBSA.

We compared the proposed FY 2014 occupational mix adjusted wage indices for each CBSA to the proposed unadjusted wage indices for each CBSA. As a result of applying the proposed occupational mix adjustment to the wage data, the proposed wage index values for 204 (52.2 percent) urban areas and 32 (66.7 percent) rural areas would increase. One hundred and eighteen (30.2 percent) urban areas would increase by 1 percent or more, and 4 (1.02 percent) urban areas would increase by 5 percent or more. Thirteen (27.1 percent) rural areas would increase by 1 percent or more, and no rural areas would increase by 5 percent or more. However, the proposed wage index values for 186 (47.6 percent) urban areas and 16 (33.3 percent) rural areas would decrease. Seventy-nine (20.2 percent) urban areas would decrease by 1 percent or more, and 1 urban area would decrease by 5 percent or more (0.26 percent). Seven (14.6 percent) rural areas would decrease by 1 percent or more, and no rural areas would decrease by 5 percent or more. The largest positive impacts are 6.61 percent for an urban area and 2.66

percent for a rural area. The largest negative impacts are 5.28 percent for an urban area and 3.17 percent for a rural area. One urban area's wage index, but no rural area wage indices, would remain unchanged by application of the proposed occupational mix adjustment. These results indicate that a larger percentage of rural areas (66.7 percent) would benefit from the proposed occupational mix adjustment than would urban areas (52.2 percent). However, approximately one-third (33.3 percent) of rural CBSAs would still experience a decrease in their proposed wage indices as a result of the proposed occupational mix adjustment.

2. Proposed Application of the Rural, Imputed, and Frontier Floors

a. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. In the proposed FY 2014 wage index associated with this proposed rule and available on the CMS Web site, we estimated that 434 hospitals would receive an increase in their FY 2014 proposed wage index due to the application of the rural floor.

b. Proposed Imputed Floor

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 three times, the last of which was adopted in the FY 2013 IPPS/LTCH PPS final rule and is set to expire on September 30, 2014 (we refer readers to the discussion in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369) and to our regulations at 42 CFR 412.64(h)(4)). There are currently two all-urban States, New Jersey and Rhode Island, that have a range of wage indices assigned to hospitals in the State, including through reclassification or redesignation (we refer readers to discussions of geographic reclassifications and redesignations in section III.H. of this preamble). However, as we explain below, the method as of FY 2012 for computing the imputed floor, which we will refer to as the original methodology, benefitted only New Jersey, and not Rhode Island.

In computing the imputed floor for an all-urban State under the original methodology, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State (that is, New Jersey and Rhode Island) as well as the average of the ratios of lowest-to-highest CBSA wage indices of those all-urban States. We compared the State's own ratio to the average ratio for all-urban States and whichever is higher was multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. Rhode Island has only one CBSA (Providence-New Bedford-Fall River, RI–MA); therefore, Rhode Island's own ratio equals 1.0, and its imputed floor was equal to its original CBSA wage index value. Conversely, New Jersey has 10 CBSAs. Because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, the original 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), for the FY 2013 wage index, the final year of the extension of the imputed floor policy under § 412.64(h)(4), we did not make any changes to the original methodology and we finalized a proposed alternative, temporary methodology for computing the imputed floor wage index to address the concern that the then-current imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indices but could not benefit the other. The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. We first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 rule, which is available 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 would then be increased by this factor, the result of which established the State's alternative imputed floor. We refer to this methodology as the alternative methodology. We also adopted a policy that, for discharges on or after October 1, 2012, and before October 1, 2013, the minimum wage index value for the State is the higher of the value determined under the original methodology or the value computed using the alternative methodology. We amended § 412.64(h)(4) of the regulations to add new paragraph (vi) to incorporate the finalized alternative methodology policies, and to make conforming references in paragraph (v).

We stated that we intended to further evaluate the need, applicability, and methodology for the imputed floor before the September 30, 2013 expiration of the imputed floor policy and address these issues in the FY 2014 proposed rule. For FY 2014, we are proposing to extend the imputed floor policy (both the original methodology and the alternative methodology) for one additional year, through September 30, 2014, while we continue to explore potential wage index reforms. We are proposing to revise the regulations at § 412.64(h)(4) to reflect the proposed 1-year extension. We are inviting public comments regarding the 1-year extension of the imputed floor.

The wage index and impact tables associated with this FY 2014 proposed rule that are available on the CMS Web site include the application of the proposed imputed floor policy at § 412.64(h)(4) and a proposed national budget neutrality adjustment for the proposed rural floor (which includes the proposed imputed floor). There are 35 hospitals in New Jersey that would receive an increase in their FY 2014 wage index due to the imputed floor policy. The proposed wage index and impact tables for this proposed rule also reflect the application of the alternative methodology for computing the imputed floor, which will benefit four hospitals in Rhode Island.

c. Proposed 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-six hospitals would receive the frontier floor value of 1.0000 for their proposed FY 2014 wage index in this proposed rule. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. Although Nevada is also defined as a frontier State, its proposed FY 2014 rural floor value of 1.1503 is greater than 1.0000, and therefore no Nevada hospitals would receive a frontier floor

value for their proposed FY 2014 wage index.

The areas affected by the proposed rural, imputed, and frontier floor policies for the proposed FY 2014 wage index are identified in Table 4D associated with this proposed rule and available on the CMS Web site.

3. Proposed FY 2014 Wage Index Tables

The proposed wage index values for FY 2014 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act), included in Tables 4A, 4B, 4C, and 4F, available on the CMS Web site, include the proposed occupational mix adjustment, geographic reclassification or redesignation as discussed in section III.H. of the preamble of this proposed rule, and the application of the rural, imputed, and frontier State floors as discussed in section III.G.2. of the preamble of this proposed rule.

Tables 3A and 3B, available on the CMS Web site, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2008, 2009, and 2010 cost reporting periods. Table 3A lists these data for urban areas, and Table 3B lists these data for rural areas. In addition, Table 2, which is available on the CMS Web site, includes the adjusted average hourly wage for each hospital from the FY 2008 and FY 2009 cost reporting periods, as well as the FY 2010 period used to calculate the proposed FY 2014 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period. The proposed average hourly wages in Tables 2, 3A, and 3B, which are available on the CMS Web site, include the proposed occupational mix adjustment. The proposed wage index values in Tables 4A, 4B, 4C, and 4D also include the proposed national rural floor budget neutrality adjustment (which includes the proposed imputed floor). The proposed wage index values in Table 2 also include the proposed out-migration adjustment for eligible hospitals.

H. 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 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 are proposing for FY 2014, 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). Also, 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 pursuant to 42 CFR 412.103.

2. FY 2014 MGCRB Reclassifications

a. FY 2014 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 outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this proposed rule was developed, the MGCRB had completed its review of FY 2014 reclassification requests. Based on such reviews, there were 332 hospitals approved for wage index reclassifications by the MGCRB for FY 2014. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2014, hospitals reclassified during FY 2012 or FY 2013 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 249 hospitals approved for wage index reclassifications in FY 2012, and 192 hospitals approved for wage index reclassifications in FY 2013. Of all the hospitals approved for reclassification for FY 2012, FY 2013, and FY 2014, based upon the review at the time of this proposed rule, 773 hospitals are in a reclassification status for FY 2014.

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications 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 2014 will be incorporated into the wage index values published in the FY 2014 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value 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.

b. Applications for Reclassifications for FY 2015

Applications for FY 2015 reclassifications are due to the MGCRB by September 3, 2013 (the first working day of September 2013). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). As mentioned in section III.B. of the preamble of this proposed rule, although OMB has

issued revisions on February 28, 2013 to its area delineations, we are not proposing to adopt those revisions for the FY 2014 wage index, and we will not be adopting the revisions before the September 3, 2013 deadline for applications for the FY 2015 wage index. Therefore, hospitals must apply for reclassifications based on the delineations we are using for FY 2014. Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2013, via the Internet on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html?redirect=/MGCRB/02_instructions_and_applications.asp*, 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. Redesignations of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA if certain criteria are met. Effective beginning FY 2005, we use OMB's 2000 CBSA standards and the Census 2000 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. (We note that, as mentioned in section III.B. of the preamble of this proposed rule, although OMB has issued revisions on February 28, 2013, to its area delineations based on 2010 census data, we are not proposing to adopt these revisions for the FY 2014 wage index.) Hospitals located in these counties have been known as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. The FY 2014 chart with 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.

4. Hospitals Redesignated Under Section 1886(d)(8)(B) of the Act Seeking Reclassification by the MGCRB

As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Using Table 4C associated with this proposed rule (which is available via the Internet on the CMS Web site), affected hospitals may compare the reclassified wage index for the labor market area into which they would be reclassified by the MGCRB to the reclassified wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals may withdraw from an MGCRB reclassification within 45 days of the publication of this FY 2014 proposed rule. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51598 through 51599) for the procedural rules and requirements for a hospital that is redesignated under section 1886(d)(8)(B) of the Act and seeking reclassification under the MGCRB, as well as our policy of measuring the urban area, exclusive of the Lugar County, for purposes of meeting proximity requirements.) We treat New England deemed counties in a manner consistent with how we treat Lugar counties. (We refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47337 through 47338) for a discussion of this policy.)

5. 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 V.E. of the preamble of this proposed rule.)

In addition, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within the requisite number of days from the publication of the proposed rule [24]) to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. That is, 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 adjustment. Thus, 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.

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.

I. Proposed FY 2014 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with the broad discretion granted to the Secretary under 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. The proposed FY 2014 out-migration adjustment is based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. (We refer readers to a full discussion of the 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 4J, which is available via the Internet on the CMS Web site, lists the proposed out-migration adjustments for the proposed FY 2014 wage index.

J. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data and occupational mix survey data files for the proposed FY 2014 wage index were made available on October 3, 2012, 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_2014_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

[24] Hospitals generally have 45 days from publication of the proposed rule to request an out-migration adjustment in lieu of the section 1886(d)(8) deemed urban status.

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 new 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 the scheduling 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 October 19, 2012, we instructed all fiscal intermediaries/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 fiscal intermediaries/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 October 3, 2012 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 10, 2012. (We note that this date was originally December 3, 2012. However, in a memorandum dated October 25, 2012, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service that we extended the deadline to December 10, 2012.) 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 October 19, 2012 memorandum referenced above.

In the October 19, 2012 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2010 occupational mix preliminary files posted to the CMS Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete documentation to its fiscal intermediary/MAC no later than December 10, 2012.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2013 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-December revision requests. The fiscal intermediaries/MACs also submitted the revised data to CMS by mid-February 2013. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 21, 2013. Hospitals had until March 4, 2013, to submit requests to the fiscal intermediaries/MACs for reconsideration of adjustments made by the fiscal intermediaries/MACs as a result of the desk review, and to correct errors due to CMS' or the fiscal intermediary's (or, if applicable, 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, fiscal intermediaries/MACs were required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 10, 2013. The deadline for a hospital to request CMS intervention in cases where the hospital disagreed with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations was April 17, 2013.

Hospitals should examine Table 2, which is listed in section VI. of the Addendum to this 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_2014_Wage_Index_Home_Page.html*. Table 2 contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2010 data used to construct the proposed FY 2014 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by March 4, 2013.

We will release the final wage index data public use files in early May 2013 on the Internet at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY_2014_Wage_Index_Home_Page.html*. The May 2013 public use files are made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary/MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the fiscal intermediaries/MACs by April 10, 2013). If, after reviewing the May 2013 final public use files, a hospital believes that its wage or occupational mix data are incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital should send a letter to both its fiscal intermediary/MAC and CMS that outlines why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). CMS and the fiscal intermediaries (or, if applicable, the MACs) must receive these requests no later than June 3, 2013.

Each request also must be sent to the fiscal intermediary/MAC. The fiscal intermediary/MAC will review requests upon receipt and contact CMS immediately to discuss any findings.

After the release of the May 2013 wage index data files, changes to the wage and occupational mix data will only be made in those very limited situations involving an error by the fiscal intermediary/MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the fiscal intermediary/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 fiscal intermediaries or the MACs on or before April 10, 2013.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 21, 2013 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the fiscal intermediary or the MAC or CMS during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS and the fiscal intermediaries or the MACs (that is, by June 3, 2013) will be incorporated into the final wage index in the FY 2014 IPPS/LTCH PPS final rule, which will be effective October 1, 2013.

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 2014 payment rates. Accordingly, hospitals that do 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 fiscal intermediary's (or, if applicable, 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 Provider Reimbursement Review Board, 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 fiscal intermediary's (or, if applicable, the MAC's) attention. Moreover, because hospitals have access to the final wage index data by early May 2013, they have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or the MAC or CMS before the development and publication of the final FY 2014 wage index by August 2013, and the implementation of the FY 2014 wage index on October 1, 2013. If hospitals avail themselves of the opportunities afforded to provide and make corrections to the wage and occupational mix data, 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 3, 2013, 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 existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The fiscal intermediary or 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 3 deadline for making corrections to the wage data for the following fiscal year's 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 fiscal intermediaries or 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 fiscal intermediary (or, if applicable, 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 fiscal intermediary (or, if applicable, 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 3, 2013 deadline for the FY 2014 wage index); and (3) CMS agreed before October 1 that the fiscal intermediary (or, if applicable, 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 3, 2013 deadline), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the fiscal intermediary's (or, if applicable, 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 judicial decision reverses a CMS denial of a hospital's wage index data revision request.

K. Labor-Related Share for the Proposed FY 2014 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: ''The Secretary shall 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 results in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43857), we rebased and revised the IPPS market basket and the labor-related share, using FY 2006 as the base year. The labor-related share for FY 2010 through FY 2013 is 68.8 percent.

For FY 2014, as described in section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the IPPS market basket using FY 2010 as the base year. Using the proposed FY 2010-based IPPS market basket, we also are proposing to recalculate the labor-related share for discharges occurring on or after October 1, 2013. As discussed in Appendix A of this proposed rule, we are proposing this revised and rebased labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we are not taking into account the additional payments that would be made as a

result of hospitals with a wage index less than or equal to 1.0 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0.

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. As described in section IV. of the preamble of this proposed rule, we are proposing to include in the labor-related share 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 as measured in the proposed IPPS market basket, as based on FY 2010. Therefore, for FY 2014, we are proposing to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2013. Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and are available via the Internet, reflect this proposed labor-related share. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this employment ''would result in lower payments to a hospital than would otherwise be made.'' Therefore, for FY 2014, for all IPPS hospitals whose wage indices are less than 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indices are greater than 1.0000, for FY 2014, we are proposing to apply the wage index to a labor-related share of 69.6 percent of the national standardized amount. We note 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 1.0.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856), we also rebased and revised the labor-related share for the Puerto Rico-specific standardized amounts using FY 2006 as a base year. We finalized a labor-related share for the Puerto Rico-specific standardized amounts for FY 2010 through FY 2013 of 62.1 percent. As described in section IV. of the preamble of this proposed rule, for FY 2014, we also are proposing to rebase and revise the labor-related share for the Puerto Rico-specific standardized amounts using FY 2010 as a base year. For FY 2014, we are proposing a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2013. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, employee benefits, contract labor, with the national proportion of costs for the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services to determine the labor-related share. 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 2014, we are proposing that the labor-related share of a hospital's Puerto Rico-specific rate will 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 of greater than 1.0 for FY 2014, we will 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 will result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than 1.0 for FY 2014 will 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 will result in higher payments. The proposed Puerto Rico labor-related share of 63.2 percent for FY 2014 is reflected in Table 1C, which is published in section VI. of the Addendum to this proposed rule and available via the Internet.

IV. Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to provide inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to provide hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. An explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). We also refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43843) in which we discussed the most recent previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use FY 2010 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index

because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods. We last rebased the hospital market basket cost weights effective for FY 2010 (74 FR 43843), with FY 2006 data used as the base period for the construction of the market basket cost weights.

B. Rebasing and Revising the IPPS Market Basket

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. ''Rebasing'' means moving the base year for the structure of costs of an input price index (for example, in this proposed rule, we are proposing to shift the base year cost structure for the IPPS hospital index from FY 2006 to FY 2010). ''Revising'' means changing data sources, or price proxies, used in the input price index. As published in the FY 2006 IPPS final rule (70 FR 47387), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket. We established a rebasing frequency of every 4 years and, therefore, for the FY 2014 IPPS update, we are proposing to rebase and revise the IPPS market basket. We are inviting public comments on our proposed methodology discussed below.

1. Development of Cost Categories and Weights

a. Medicare Cost Reports

The major source of expenditure data for developing the rebased and revised hospital market basket cost weights is the FY 2010 Medicare cost reports. These FY 2010 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2009 and before October 1, 2010. We are proposing to use FY 2010 as the base year because we believe that the FY 2010 Medicare cost reports represent the most recent, complete set of Medicare cost report data available for IPPS hospitals. As was done in previous rebasings, these cost reports are from IPPS hospitals only (hospitals excluded from the IPPS and CAHs are not included) and are based on IPPS Medicare-allowable operating costs. IPPS Medicare-allowable operating costs are costs that are eligible to be paid for under the IPPS. For example, the IPPS market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS and, therefore, these costs are not IPPS Medicare-allowable costs.

We are proposing to obtain seven major expenditures or cost categories for the FY 2010 IPPS market basket from the Medicare cost reports—the same as in the FY 2006-based hospital market basket: wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance (malpractice), blood and blood products, and a residual ''all other.'' The proposed cost weights that were obtained directly from the Medicare cost reports are reported in Table IV01. We are proposing to then supplement these Medicare cost report cost weights with information obtained from other data sources to derive the proposed IPPS market basket cost weights.

TABLE IV01—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM THE MEDICARE COST REPORTS

Major cost categories	FY 2006-based market basket	Proposed FY 2010-based market basket
Wages and salaries	45.156	45.819
Employee benefits	11.873	12.713
Contract labor	2.598	1.806
Professional Liability Insurance (Malpractice)	1.661	1.330
Pharmaceuticals	5.380	5.402
Blood and blood products	1.078	1.069
All other	32.254	31.861

From FY 2006 to FY 2010, the wages and salaries and employee benefits cost weights as calculated directly from the Medicare cost reports increased by approximately 0.7 and 0.8 percentage point, respectively, while the contract labor cost weight decreased by 0.8 percentage point. As we did for the FY 2006-based IPPS market basket (74 FR 43847), we are proposing to allocate contract labor costs to the wages and salaries and employee benefits cost weights based on their relative proportions for employed labor under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the wages and salaries cost weight as a percent of the sum of the wages and salaries cost weight and the employee benefits cost weight. Using the FY 2010 Medicare cost report data, this percentage is 78.3 percent; therefore, we are proposing to allocate approximately 78.3 percent of the contract labor cost weight to the wages and salaries cost weight. Table IV02 shows the wages and salaries and employee benefit cost weights after contract labor allocation for both the FY 2006-based IPPS market basket and the proposed FY 2010-based IPPS market basket.

TABLE IV02—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	FY 2006-based market basket	Proposed FY 2010-based market basket
Wages and salaries	47.213	47.233
Employee benefits	12.414	13.105

After the allocation of contract labor, the proposed FY 2010-based wages and salaries cost weight is relatively similar to the FY 2006-based wages and salaries cost weight while the proposed FY 2010-based employee benefits cost weight increased 0.7 percentage point. This is primarily a result of an increase in benefits costs relative to wages and salaries costs from the Medicare cost report data for employed workers; in 2006, the ratio of the employee benefits cost weight to the wages and salaries cost weight was 26.3 percent while in 2010, this ratio increased to 27.8 percent.

b. Other Data Sources

In addition to the data from the Medicare cost reports, the other data source we are proposing to use to develop the FY 2010-based IPPS market basket cost weights is the 2002 Benchmark Input-Output (I–O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. We are proposing to use the 2002 BEA Benchmark I–O data to disaggregate the ''all other'' (residual) cost category (31.861 percent) into more detailed hospital expenditure category shares. The BEA Benchmark I–O accounts provide the most detailed information on the goods and services purchased by an industry, which allows for a more detailed disaggregation of expenses in the market basket for which we can then proxy the appropriate price inflation.

The BEA Benchmark I–O data are generally scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I–O estimates; however, the 2002 Benchmark I–O data represent a much more comprehensive and detailed set of data that are derived from the 2002 Economic Census. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43845), we used the 2002 Benchmark I–O data (aged to FY 2006) for the FY 2006-based IPPS market basket, to be effective for FY 2010. Because BEA has not yet released new Benchmark I–O data, and we believe the data to be comprehensive and complete as indicated above, we are currently proposing to use the 2002 Benchmark I–O data in the FY 2010-based IPPS market basket.

Therefore, instead of using the less detailed, less accurate Annual I–O data, we are proposing to age the 2002 Benchmark I–O data forward to FY 2010. The methodology we are proposing to use to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeat this practice for each year. We also are proposing that, if more recent BEA benchmark I–O data for 2007 is released between the proposed and final rule with sufficient time to incorporate such data into the final rule, we would incorporate these data into the FY 2010-based IPPS market basket for the final rule. The 2007 BEA I–O data is expected to be released in the summer of 2013.

The ''all other'' cost category expenditure shares are determined as being equal to each category's proportion to total ''all other'' expenditures based on the aged 2002 Benchmark I–O data. For instance, if the cost for telephone services represented 10 percent of the sum of the ''all other'' Benchmark I–O hospital expenditures, telephone services would represent 10 percent of the ''all other'' cost category of the proposed IPPS market basket.

Following publication of the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, and in an effort to provide greater transparency, we posted on the CMS market basket Web page at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* an illustrative spreadsheet that shows how the detailed cost weights in the proposed rule (that is, those not calculated using Medicare cost reports) were determined using the 2002 Benchmark I–O data. As stated above, we are proposing to use the 2007 Benchmark BEA I–O data if available before the final rule with sufficient time to incorporate such data into the final rule. We would use the same methodology as described above in determining the detailed weights in the ''all other'' cost weight.

2. Cost Category Computation

As stated previously, for the proposed FY 2010-based market basket we are proposing to use data from the Medicare cost reports to derive seven major cost categories. We are proposing the same detailed cost categories as the FY 2006-based IPPS market basket. Also, we are not proposing to change our definition of the labor-related share. As discussed in more detail below and similar to the previous rebasing, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market.

3. Selection of Price Proxies

After computing the FY 2010 cost weights for the proposed IPPS market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. We are proposing to use the same price proxies that were used in the FY 2006-based IPPS market basket. A discussion of our rationale for selecting these price proxies can be found in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43845).

With the exception of the proxy for professional liability insurance (PLI), all the proxies we are proposing are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- Producer Price Indexes—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we are proposing to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we are proposing to use measure price changes at the final stage of production.
- Consumer Price Indexes—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not

represent the price faced by a producer, we are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is proposed to be used as a proxy for contracted food services.

• Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table IV03 below sets forth the proposed FY 2010-based IPPS market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2006-based IPPS market basket cost weights also are listed. A summary outlining the choice of the various proxies follows the table.

TABLE IV03—PROPOSED FY 2010-BASED IPPS HOSPITAL MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO FY 2006-BASED IPPS MARKET BASKET COST WEIGHTS

Cost categories	FY 2006-based hospital market basket cost weights	Proposed FY 2010-based hospital market basket cost weights	Proposed FY 2010-based hospital market basket price proxies
1. Compensation	59.627	60.338	
A. Wages and Salaries [1]	47.213	47.233	ECI for Wages and Salaries, Civilian Hospital Workers.
B. Employee Benefits [1]	12.414	13.105	ECI for Benefits, Civilian Hospital Workers.
2. Utilities	2.180	2.246	
A. Fuel, Oil, and Gasoline	0.418	0.447	PPI for Petroleum Refineries.
B. Electricity	1.645	1.666	PPI for Commercial Electric Power.
C. Water and Sewage	0.117	0.133	CPI–U for Water & Sewerage Maintenance.
3. Professional Liability Insurance	1.661	1.330	CMS Professional Liability Insurance Premium Index.
4. All Other	36.533	36.086	
A. All Other Products	19.473	19.458	
(1.) Pharmaceuticals	5.380	5.402	PPI for Pharmaceuticals for Human Use, Prescription.
(2.) Food: Direct Purchases	3.982	4.206	PPI for Processed Foods & Feeds.
(3.) Food: Contract Services	0.575	0.578	CPI–U for Food Away From Home.
(4.) Chemicals [2]	1.538	1.529	Blend of Chemical PPIs.
(5.) Blood and Blood Products	1.078	1.069	PPI for Blood and Organ Banks.
(6.) Medical Instruments	2.762	2.577	PPI for Medical, Surgical, and Personal Aid Devices.
(7.) Rubber and Plastics	1.659	1.637	PPI for Rubber & Plastic Products.
(8.) Paper and Printing Products.	1.492	1.507	PPI for Converted Paper & Paperboard Products.
(9.) Apparel	0.325	0.299	PPI for Apparel.
(10.) Machinery and Equipment	0.163	0.151	PPI for Machinery & Equipment.
(11.) Miscellaneous Products	0.519	0.503	PPI for Finished Goods less Food and Energy.
B. Labor-related Services	9.175	9.249	
(1.) Professional Fees: Labor-related.	5.356	5.500	ECI for Compensation for Professional and Related Occupations.
(2.) Administrative and Facilities Support Services [3].	0.626	0.619	ECI for Compensation for Office and Administrative Services.
(3.) All Other: Labor-Related Services.	3.193	3.130	ECI for Compensation for Private Service Occupations.
C. Nonlabor-Related Services	7.885	7.379	
(1.) Professional Fees: Nonlabor-Related.	4.074	3.687	ECI for Compensation for Professional and Related Occupations.
(2.) Financial Services	1.281	1.239	ECI for Compensation for Financial Activities.
(3.) Telephone Services	0.627	0.597	CPI–U for Telephone Services.
(4.) Postage	0.963	0.956	CPI–U for Postage.
(5.) All Other: Nonlabor-Related Services.	0.940	0.900	CPI–U for All Items less Food and Energy.
Total	100.000	100.000	

Note: Detail may not add to total due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

[2] To proxy the ''chemicals'' cost category, we used a blended PPI composed of the PPI for industrial gas manufacturing, the PPI for other basic inorganic chemical manufacturing, the PPI for other basic organic chemical manufacturing, and the PPI for soap and cleaning compound manufacturing. For more detail about this proxy, see the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43845).

[3] We note that this cost category in the FY 2006-based IPPS market basket was ''Administrative and Business Support Services.'' We changed the name slightly to be more clear what type of costs are included in this cost category, but we did not change the classification of which costs are included in the category.

As stated above, we are proposing to use the same price proxies used in the FY 2006-based IPPS market basket. A rationale for selecting these price proxies can be found in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43845). The price proxies we are proposing were selected to most closely match the costs included in each of the cost categories of the proposed FY 2010-based IPPS market basket. As discussed above, we are proposing that, if the 2007 Benchmark I–O data become available between the proposed and final rule with sufficient time to incorporate such data into the final rule, we would incorporate this data into the FY 2010-based IPPS market basket for the final rule. As a result, to the extent the incorporation of the 2007 Benchmark I–O data results in a different composition of costs included in a particular cost category, we are proposing that we may choose to revise that specific price proxy to ensure that the costs included in each detailed cost category are best aligned with the associated price proxy. Below is a list of the price proxies we are proposing for the FY 2010-based IPPS market basket.

a. Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category.

b. Employee Benefits

We are proposing to use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category.

c. Fuel, Oil, and Gasoline

We are proposing to use the PPI for Petroleum Refineries (BLS series code PCU324110324110) to measure the price growth of this cost category.

d. Electricity

We are proposing to use the PPI for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category.

e. Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category.

f. Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Insurance Premium Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price changes in the Medicare Economic Index (75 FR 73268).

g. Pharmaceuticals

We are proposing to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy that was used in the FY 2006-based IPPS market basket, although BLS since changed the naming convention for this series.

h. Food: Direct Purchases

We are proposing to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category.

i. Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category.

j. Chemicals

We are proposing to use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561–).

k. Blood and Blood Products

We are proposing to use the PPI for Blood and Organ Banks (BLS series code PCU621991621991) to measure the price growth of this cost category.

l. Medical Instruments

We are proposing to use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category.

m. Rubber and Plastics

We are proposing to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category.

n. Paper and Printing Products

We are proposing to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category.

o. Apparel

We are proposing to use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category.

p. Machinery and Equipment

We are proposing to use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category.

q. Miscellaneous Products

We are proposing to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category.

r. Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIU2010000120000I) to measure the price growth of these cost categories.

s. Administrative and Facilities Support Services

We are proposing to use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category.

t. All Other: Labor-Related Services

We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.

u. Financial Services

We are proposing to use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category.

v. Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category.

w. Postage

We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category.

x. All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category.

Table IV04 compares both the historical and forecasted percent changes in the FY 2006-based IPPS market basket and the proposed FY 2010-based IPPS market basket.

TABLE IV04—FY 2006-BASED AND PROPOSED FY 2010-BASED PROSPECTIVE PAYMENT HOSPITAL OPERATING INDEX PERCENT CHANGE, FY 2008 THROUGH FY 2016

Fiscal year (FY)	FY 2006-based IPPS market basket operating index percent change	Proposed FY 2010-based IPPS market basket operating index percent change
Historical data:		
FY 2008	4.0	4.0
FY 2009	2.6	2.6
FY 2010	2.1	2.1
FY 2011	2.7	2.7
FY 2012	2.2	2.2
Average FYs 2008–2012	2.7	2.7
Forecast:		
FY 2013	2.2	2.2
FY 2014	2.5	2.5
FY 2015	2.7	2.7
FY 2016	3.0	3.0
Average FYs 2013–2016	2.6	2.6

Source: IHS Global Insight, Inc., 1st Quarter 2013.

The differences between the FY 2006-based and the proposed FY 2010-based IPPS market basket increases are minimal. While the percent changes differ slightly, when rounded to the nearest tenth, the updates based on the FY 2006-based and the proposed FY 2010-based IPPS market baskets are the same.

4. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments that are labor-related. ''The Secretary shall 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 proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.''

The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market.* Because of this approach, we are proposing to include in the labor-related share 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, as we did in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850). Consistent with previous rebasings, the ''all other: labor-related services'' cost category is mostly comprised of building maintenance and security services (including, but not limited to, commercial and industrial machinery and equipment repair, nonresidential maintenance and repair, and investigation and security services). Because these services tend to be labor-intensive and are mostly performed at the hospital facility (and, therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

Similar to the FY 2006-based IPPS market basket, we are proposing that the professional fees: labor-related cost category includes expenses associated with advertising and a proportion of legal services, accounting and auditing, engineering, management consulting, and management of companies and enterprises expenses. As was done in the FY 2006-based IPPS market basket rebasing, we are proposing to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments (71 FR 8588).

With approval from the OMB, we contacted the industry and received responses to our survey from 108 hospitals. Using data on FTEs to allocate responding hospitals across strata (region of the country and urban/rural status), we calculated poststratification weights. A more thorough discussion of the composition of the survey and poststratification can be found in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services;
- 30 percent of engineering services;
- 33 percent of legal services; and
- 42 percent of management consulting services.

We are proposing to apply each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category. This is the methodology that we used to separate the FY 2006-based IPPS market basket professional fees category into professional fees: labor-related and professional fees: nonlabor-related cost categories. We are proposing to use the same methodology and survey results to separate the FY 2010-based IPPS market basket professional fees category into professional fees: labor-related and professional fees: nonlabor-related cost categories. We believe these survey results are appropriate to use for the FY

2010-based IPPS market basket rebasing as they empirically determine the proportion of contracted professional services purchased by the industry that is attributable to local firms and the proportion that is purchased from national firms.

In the proposed FY 2010-based IPPS market basket, nonmedical professional fees that were subject to allocation based on the survey results represent 2.059 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we are apportioning 1.301 percentage points of the 2.059 percentage point figure into the labor-related share and designating the remaining 0.758 percentage point as nonlabor-related.

In addition to the professional services listed above, we also classify a proportion of the expenses under NAICS 55, Management of Companies and Enterprises, into the professional fees: labor-related cost category as was done in the previous rebasing. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. As was done for the FY 2006-based IPPS market basket we are proposing to include only a portion of the home office costs in the labor related share as not all hospitals are located in the same geographic area as their home office.

Our proposed methodology is based on data from the Medicare cost reports, as well as a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and State information (addresses) for home offices). The Medicare cost report requires hospitals to report their home office provider numbers and locations. Using the data reported on the Medicare Cost Report as well as the HOMER database to determine the home office location for each home office provider number, we compared the location of the hospital with the location of the hospital's home office. We determined the proportion of costs that should be allocated to the labor-related share based on the percent of total hospital home office compensation costs for those hospitals that had home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA). We primarily determined a hospital's and home office's MSAs using their zip code information from the Medicare cost report. For any home offices for which we could not identify a MSA from the Medicare cost report, we used the Medicare HOMER database to identify the home office's city and State.

We are proposing to determine the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office compensation as reported in Worksheet S–3, part II. Using this proposed methodology, we determined that 62 percent of hospitals' home office compensation costs were for home offices located in their respective local labor markets, and therefore, we are proposing to allocate 62 percent of NAICS 55 expenses to the labor-related share.

In the proposed FY 2010-based IPPS market basket, NAICS 55 expenses that were subject to allocation based on the home office allocation methodology represent 5.650 percent of the total operating costs. Based on the home office results, we are apportioning 3.503 percentage points of the 5.650 percentage points figure into the labor-related share and designating the remaining 2.147 percentage points as nonlabor-related. In sum, based on the two proposed allocations mentioned above, we are proposing to apportion 4.804 percentage points into the labor-related share. This amount is added to the 0.696 percentage point of professional fees that we already identified as labor-related, resulting in a proposed professional fees: labor-related cost weight of 5.500 percent.

Below is a table comparing the proposed FY 2010-based labor-related share and the FY 2006-based labor-related share. As discussed in section IV.B.3. of the preamble of this proposed rule, the wages and salaries and employee benefits cost weight reflect contract labor costs.

TABLE IV05—COMPARISON OF THE PROPOSED FY 2010-BASED LABOR-RELATED SHARE AND THE FY 2006-BASED LABOR-RELATED SHARE

	FY 2006-based market basket cost weights	Proposed FY 2010-based market basket cost weights
Wages and Salaries	47.213	47.233
Employee Benefits	12.414	13.105
Professional Fees: Labor-Related	5.356	5.500
Administrative and Facilities		
Support Services	0.626	0.619
All Other: Labor-Related Services	3.193	3.130
Total Labor-Related Share	68.802	69.587

Using the cost category weights from the proposed FY 2010-based IPPS market basket, we calculated a labor-related share of 69.587 percent, approximately 0.8 percentage point higher than the current labor-related share of 68.802.

We continue to believe, as we have stated in the past, that these operating cost categories are related to, influenced by, or vary with the local markets. Therefore, our definition of the labor-related share continues to be consistent with section 1886(d)(3) of the Act.

Using the proposed cost category weights that we determined in section IV.B.1. of the preamble of this proposed rule, we calculated a proposed labor-related share of 69.587 percent, using the proposed FY 2010-based IPPS market basket. Accordingly, we are proposing to implement a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2013.

We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless 62 percent ''would result in lower payments to a hospital than would otherwise be made.''

We also are proposing to update the labor-related share for Puerto Rico. Consistent with our methodology for determining the national labor-related

share, we calculate the Puerto Rico-specific relative weights for wages and salaries, employee benefits, and contract labor using FY 2010 Medicare cost report data for IPPS hospitals located in Puerto-Rico. Because there are no Puerto Rico-specific relative weights for professional fees and labor intensive services, we use the national weights as shown in Table IV05. This is the same methodology we used to determine the FY 2006-based Puerto Rico-specific labor-related share derived during the FY 2006-based IPPS market basket rebasing (74 FR 43856).

Below is a table comparing the proposed FY 2010-based Puerto Rico-specific labor-related share and the FY 2006-based Puerto Rico-specific labor-related share.

TABLE IV06—COMPARISON OF THE PROPOSED FY 2010-BASED PUERTO RICO-SPECIFIC LABOR-RELATED SHARE AND FY 2006-BASED PUERTO RICO-SPECIFIC LABOR-RELATED SHARE

	FY 2006-based market basket cost weights	Proposed FY 2010-based market basket cost weights
Wages and Salaries	44.221	44.918
Benefits	8.691	8.990
Professional Fees: Labor-Related	5.356	5.500
Administrative and Facilities Support Services	0.626	0.619
All Other: Labor-Related Services	3.193	3.130
Total Labor-Related Share	62.087	63.157

Using the proposed FY 2010-based Puerto Rico cost category weights, we calculated a labor-related share of 63.157 percent, approximately 1.1 percentage points higher than the current Puerto-Rico specific labor-related share of 62.087. Accordingly, we are proposing to adopt an updated Puerto Rico labor-related share of 63.2 percent.

C. Market Basket for Certain Hospitals Presently Excluded From the IPPS

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857), we adopted the use of the FY 2006-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals and religious nonmedical health care institutions (RNHCIs). Children's hospitals and PPS-excluded cancer hospitals and RNHCIs are still reimbursed solely under the reasonable cost-based system, subject to the rate-of-increase limits. Under these limits, an annual target amount (expressed in terms of the inpatient operating cost per discharge) is set for each hospital based on the hospital's own historical cost experience trended forward by the applicable rate-of-increase percentages.

Under the broad authority in sections 1886(b)(3)(A) and (B), 1886(b)(3)(E), and 1871 of the Act and section 4454 of the BBA, consistent with our use of the IPPS operating market basket percentage increase to update target amounts, we are proposing to use the FY 2010-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, 11 PPS-excluded cancer hospitals, and RNHCIs that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40.

Due to the small number of children's and cancer hospitals and RNHCIs that receive, in total, less than 1 percent of all Medicare payments to hospitals and because these hospitals provide limited Medicare cost report data, we are unable to create a separate market basket specifically for these hospitals. Due to the limited cost report data available, we believe that the proposed FY 2010-based IPPS operating market basket most closely represents the cost structure of children's hospitals, PPS-excluded cancer hospitals, and RNHCIs. We believe this is appropriate as the IPPS operating market basket would reflect the input price growth for providing inpatient hospital services (similar to the services provided by the above excluded hospitals) based on the specific mix of goods and services required. Therefore, we believe that the percentage change in the proposed FY 2010-based IPPS operating market basket is the best available measure of the average increase in the prices of the goods and services purchased by the 11 cancer hospitals, children's hospitals, and RNHCIs in order to provide care.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule (57 FR 40016). There have been subsequent discussions of the CIPI presented in the IPPS proposed and final payment rules. The FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857) discussed the most recent rebasing and revision of the CIPI to a FY 2006 base year, which reflected the capital cost structure of the hospital industry in that year.

For the FY 2014 IPPS update, we are proposing to rebase and revise the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. As with the FY 2006-based index, we developed two sets of weights in order to calculate the proposed FY 2010-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each expenditure category, while the second set of weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of the capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Both sets of weights are developed using the best data sources available. In reviewing source data, we determined that the Medicare cost reports provided accurate data for all capital expenditure cost categories. We used the FY 2010 Medicare cost reports for IPPS hospitals to determine weights for all three cost categories: depreciation, interest, and other capital expenses.

Lease expenses are unique in that they are not broken out as a separate cost category in the CIPI, but rather are proportionally distributed among the cost categories of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure and price movement of leases is similar to that of capital costs in general. As was done in previous rebasings of the CIPI, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the Other category accordingly. The remaining

lease expenses were distributed across the three cost categories based on the respective weights of Depreciation, Interest, and Other not including lease expenses.

Depreciation contains two subcategories: (1) Building and Fixed equipment; and (2) Movable Equipment. The proposed apportionment between building and fixed equipment and movable equipment was determined using the Medicare cost reports. This methodology was also used to compute the apportionment used in the FY 2006-based index.

The total Interest cost category is split between government/nonprofit interest and for-profit interest. The FY 2006-based CIPI allocated 85 percent of the total interest cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 15 percent of the interest cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (74 FR 43857).

For the FY 2010-based CIPI, we are proposing to derive the split using the relative FY 2010 Medicare cost report data on interest expenses for government/nonprofit and for-profit hospitals. Based on these data, we calculated an 89/11 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses.

Table IV07 presents a comparison of the proposed FY 2010-based CIPI cost weights and the FY 2006-based CIPI cost weights.

TABLE IV07—PROPOSED FY 2010-BASED CIPI COST CATEGORIES, WEIGHTS, AND PRICE PROXIES WITH FY 2006-BASED CIPI INCLUDED FOR COMPARISON

Cost categories	FY 2006 weights	Proposed FY 2010 weights	Price proxy
Total	100.00	100.00	
Total depreciation	75.154	74.011	
Building and fixed equipment depreciation.	35.789	36.153	BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage-weighted (26 years).
Movable equipment depreciation	39.365	37.858	PPI for machinery and equipment—vintage-weighted (12 years).
Total interest	17.651	19.157	
Government/nonprofit interest	15.076	17.051	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage-weighted (26 years).
For-profit interest	2.575	2.106	Average yield on Moody's Aaa bonds—vintage-weighted (26 years).
Other	7.195	6.832	CPI–U for residential rent.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We used the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense. Following publication of the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, and in order to provide greater transparency, we posted on the CMS market basket Web page at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* an illustrative spreadsheet that contains an example of how the vintage-weighted price indexes are calculated.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. The CIPI accurately reflects the annual price changes associated with capital costs, and is a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate, stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The CIPI reflects the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides a uniquely best time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital purchases. However, AHA does provide a consistent database back to 1963. We used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2010.

In order to estimate capital purchases using data on depreciation expenses, the expected life for each cost category (building and fixed equipment, movable equipment, and interest) is needed to calculate vintage weights. We used FY 2010 Medicare cost reports to determine the expected life of building and fixed equipment and of movable equipment. The expected life of any piece of equipment can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. From the FY 2010 Medicare cost reports, the proposed expected life of building and fixed equipment was determined to be 26 years, and the proposed expected life of movable equipment was determined to be 12

years. The FY 2006-based CIPI was based on an expected life of building and fixed equipment of 25 years and 12 years as the expected life for movable equipment.

We are proposing to use the building and fixed equipment and movable equipment weights derived from FY 2010 Medicare cost reports to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. Year-end asset costs for building and fixed equipment and movable equipment were determined by multiplying the annual depreciation amounts by the expected life calculations from the FY 2010 Medicare cost reports. We then calculated a time series back to 1963 of annual capital purchases by subtracting the previous year asset costs from the current year asset costs. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

For building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, BEA's chained price index for nonresidential construction for hospitals and special care facilities. Because building and fixed equipment have an expected life of 26 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 26-year periods. With real building and fixed equipment purchase estimates available back to 1963, we averaged twenty-two 26-year periods to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period, and for each of the twenty-two 26-year periods. We used the average of each year across the twenty-two 26-year periods to determine the average building and fixed equipment vintage weights for the proposed FY 2010-based CIPI.

For movable equipment vintage weights, the real annual capital purchase amounts for movable equipment were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for machinery and equipment. Based on our determination that movable equipment has an expected life of 12 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over a 12-year period. With real movable equipment purchase estimates available back to 1963, thirty-six 12-year periods were averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 12-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 12-year period. This calculation was done for each year in the 12-year period and for each of the thirty-six 12-year periods. We used the average of each year across the thirty-six 12-year periods to determine the average movable equipment vintage weights for the proposed FY 2010-based CIPI.

For interest vintage weights, the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) were used to capture the value of the debt instrument. Because we have determined that hospital debt instruments have an expected life of 26 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 26-year periods. With nominal total equipment purchase estimates available back to 1963, twenty-two 26-year periods were averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period and for each of the twenty-two 26-year periods. We used the average of each year across the twenty-two 26-year periods to determine the average interest vintage weights for the proposed FY 2010-based CIPI.

The vintage weights for the FY 2006-based CIPI and the proposed FY 2010-based CIPI are presented in Table IV08.

TABLE IV08—FY 2006 VINTAGE WEIGHTS AND PROPOSED FY 2010 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	FY 2006 25 years	FY 2010 26 years	FY 2006 12 years	FY 2010 12 years	FY 2006 25 years	FY 2010 26 years
1	0.021	0.023	0.063	0.064	0.010	0.012
2	0.023	0.024	0.067	0.068	0.012	0.013
3	0.025	0.026	0.071	0.071	0.014	0.015
4	0.027	0.028	0.075	0.073	0.016	0.017
5	0.029	0.029	0.079	0.076	0.018	0.018
6	0.031	0.031	0.082	0.078	0.020	0.021
7	0.032	0.032	0.085	0.084	0.023	0.023
8	0.033	0.034	0.086	0.088	0.025	0.025
9	0.036	0.036	0.090	0.092	0.028	0.028
10	0.038	0.038	0.093	0.098	0.031	0.030
11	0.040	0.040	0.102	0.103	0.034	0.033
12	0.042	0.041	0.106	0.106	0.038	0.036
13	0.044	0.042	.....	.....	0.041	0.038
14	0.045	0.042	.....	.....	0.044	0.040
15	0.046	0.043	.....	.....	0.047	0.043

TABLE IV08—FY 2006 VINTAGE WEIGHTS AND PROPOSED FY 2010 VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES—Continued

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	FY 2006 25 years	FY 2010 26 years	FY 2006 12 years	FY 2010 12 years	FY 2006 25 years	FY 2010 26 years
16	0.047	0.044			0.050	0.045
17	0.048	0.044			0.053	0.047
18	0.050	0.044			0.057	0.048
19	0.050	0.044			0.059	0.051
20	0.050	0.044			0.060	0.052
21	0.048	0.045			0.060	0.056
22	0.048	0.045			0.062	0.057
23	0.047	0.045			0.063	0.060
24	0.049	0.046			0.068	0.062
25	0.048	0.045			0.069	0.064
26		0.045				0.066
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Detail may not add to total due to rounding.
[1] Year 1 represents the vintage weight applied to the farthest year while the vintage weight for year 26, for example, would apply to the most recent year.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. We are proposing to use the same price proxies for the FY 2010-based CIPI that were used in the FY 2006-based CIPI. The rationale for selecting the price proxies was explained more fully in the FY 1997 IPPS final rule (61 FR 46196) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857). These proposed price proxies are presented in Table IV07.

Table IV09 below compares both the historical and forecasted percent changes in the FY 2006-based CIPI and the proposed FY 2010-based CIPI.

TABLE IV09—COMPARISON OF FY 2006-BASED AND PROPOSED FY 2010-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2008 THROUGH FY 2016

Fiscal year	CIPI, FY 2006-based	Proposed CIPI, FY 2010-based
FY 2008	1.5	1.1
FY 2009	1.5	1.2
FY 2010	1.0	0.7
FY 2011	1.2	0.9
FY 2012	1.2	1.0
Forecast:		
FY 2013	1.2	1.0
FY 2014	1.4	1.2
FY 2015	1.5	1.3
FY 2016	1.7	1.5
Average:		
FYs 2008–2012	1.3	1.0
FYs 2013–2016	1.5	1.3

Source: IHS Global Insight, Inc., 1st Quarter 2013 forecast.

IHS Global Insight, Inc. forecasts a 1.2 percent increase in the FY 2010-based CIPI for FY 2014, as shown in Table IV09. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) are included in Table IV10.

TABLE IV10—CMS CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS—FYS 2008 THROUGH 2016

Fiscal year	Total	Depreciation	Interest
FY 2008	1.1	2.0	−3.1
FY 2009	1.2	2.0	−2.0
FY 2010	0.7	1.7	−2.8
FY 2011	0.9	1.7	−2.3
FY 2012	1.0	1.7	−2.7
Forecast:			
FY 2013	1.0	1.7	−2.8

TABLE IV10—CMS CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS—FYS 2008 THROUGH 2016—Continued

Fiscal year	Total	Depreciation	Interest
FY 2014	1.2	1.8	−2.3
FY 2015	1.3	1.9	−1.7
FY 2016	1.5	1.9	−0.7

Source: IHS Global Insight, Inc., 1st Quarter 2013 forecast

Rebasing the CIPI from FY 2006 to FY 2010 decreased the percent change in the forecasted update for FY 2014 by 0.2 percentage point, from 1.4 percent to 1.2 percent, as shown in Table IV09. The difference in the forecasted market basket update for FY 2014 is primarily due to the rebasing of the index to FY 2010 and revising the base year cost weights to incorporate the FY 2010 Medicare cost report data.

V. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

A. Proposed Changes in the Inpatient Hospital Update for FY 2014 (§§ 412.64(d) and 412.211(c))

1. Proposed FY 2014 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.'' Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2014 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) 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 0.3 percentage point. 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 2014 adjustment of 0.3 percentage point may result in the applicable percentage increase being less than zero.

We note, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace 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.

We also are proposing to rebase the labor-related share to reflect the more recent base year. The current labor-related share, which is based on the FY 2006-based IPPS market basket, is 68.8 percent. We are proposing a labor-related share of 69.6 percent, which is based on the proposed rebased and revised FY 2010-based IPPS market basket. For a complete discussion on the rebasing of the market basket and labor-related share, we refer readers to section IV. of the preamble of this proposed rule.

Based on the most recent data available for this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2014 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) first quarter 2013 forecast of the FY 2010-based IPPS market basket rate-of-increase, which is estimated to be 2.5 percent. 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. For FY 2014, we are not proposing any change in our methodology for calculating and applying the MFP adjustment. However, for this proposed rule, we are using the most recent data available to compute the MFP adjustment. Using the methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51690), the proposed FY 2014 market basket update, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, is then reduced by the most recent estimate of the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2014) of 0.4 percent. Following application of the MFP adjustment, the applicable percentage increase is then reduced by 0.3 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act (as discussed in section I. of the Addendum to this proposed rule).

Consistent with current law, and based on IGI's first quarter 2013 forecast of the FY 2014 market basket increase, we are proposing an applicable percentage increase to the FY 2014 operating standardized amount of 1.8 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for economy-wide productivity (that is, the MFP adjustment) and less 0.3 percentage point) for hospitals in all areas, provided the hospital submits quality data under rules established in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that do not submit these quality data, we are proposing an applicable percentage increase to the operating standardized amount of −0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.4 percentage point for the MFP adjustment, and less an additional adjustment of 0.3 percentage point). Lastly, we also are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2014 market basket update and MFP adjustment in the final rule.

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2014 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to add a new paragraph (v) to § 412.64(d)(1) to reflect the applicable percentage increase to the FY 2014 operating standardized amount as the percentage increase in the market basket index less an MFP adjustment and less an additional reduction of 0.3 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs 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 is also 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, we are proposing an update to the hospital-specific rates applicable to SCHs of 1.8 percent for hospitals that submit quality data or −0.2 percent for hospitals that fail to submit quality data. For FY 2014, the existing regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e) and 412.78(e) contain provisions that set the update factor for SCHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make any further changes to these four regulatory provisions to reflect the FY 2014 update factor for the hospital-specific rates of SCHs.

We note that, as discussed in section V.F. of this preamble, section 606 of the American Taxpayer Relief Act of 2012 extended the MDH program from the end of FY 2012 (that is, for discharges occurring before October 1, 2012) to the end of FY 2013 (that is, for discharges occurring before October 1, 2013). Under prior law, the MDH program was to be in effect through the end of FY 2012 only. Absent additional legislation further extending the MDH program, the MDH program will expire for discharges beginning in FY 2014. Accordingly, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2014.

2. Proposed FY 2014 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, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.8 percent for FY 2014. The regulations at § 412.211(c) currently set the update factor for the Puerto Rico-specific operating standardized amount equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, it is not necessary to propose any changes to the existing regulatory text.

B. Rural Referral Centers (RRCs): Proposed Annual Update 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 are also 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 where the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, ''[a]ny hospital classified as an RRC by the Secretary . . . for fiscal year 1991 shall be classified as such an RRC for fiscal year 1998 and each subsequent year.'' In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost the 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 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).) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2014 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2014 are the median CMI values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2012 (October 1, 2011 through September 30, 2012), and include bills posted to CMS' records through December 2012.

We are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting

periods beginning on or after October 1, 2013, they must have a CMI value for FY 2012 that is at least—

- 1.5526; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed 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)	1.3319
2. Middle Atlantic (PA, NJ, NY)	1.4025
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4799
4. East North Central (IL, IN, MI, OH, WI)	1.4542
5. East South Central (AL, KY, MS, TN)	1.4266
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.5311
7. West South Central (AR, LA, OK, TX)	1.5811
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6393
9. Pacific (AK, CA, HI, OR, WA)	1.5568

We intend to update the preceding numbers in the FY 2014 final rule to reflect the updated FY 2012 MedPAR file, which would contain data from additional bills received through March 2013.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or 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 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. We would normally propose to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2011 (that is, October 1, 2010 through September 30, 2011), which would normally be the latest cost report data available at the time of the development of this proposed rule. However, due to a transition in our data system, in lieu of a full year of FY 2011 cost report data, we are proposing to use a combination of FY 2010 and FY 2011 cost report data in order to create a full fiscal year of cost report data for this analysis. Due to CMS' transition to a new cost reporting form effective for cost reporting periods beginning on or after May 1, 2010, some FY 2011 cost reports were not yet in our system for analysis at the time of the development of this proposed rule. Therefore, in order to have a complete fiscal year of cost report data, we utilized FY 2011 cost report data if available, and for those providers whose FY 2011 cost report data was not yet in our system, we utilized their FY 2010 cost report data. This is similar to the process we used to establish the median number of discharges for urban hospitals in the census region for FY 2013, where we utilized FY 2009 and 2010 cost report data (77 FR 53406).

We are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2013, must have, as the number of discharges for its cost reporting period that began during FY 2011 (based on a combination of FY 2010 and FY 2011 cost report data as explained in the preceding paragraph), 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, as indicated in the following table:

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,825
2. Middle Atlantic (PA, NJ, NY)	10,891
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,566
4. East North Central (IL, IN, MI, OH, WI)	8,360
5. East South Central (AL, KY, MS, TN)	7,378
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,747
7. West South Central (AR, LA, OK, TX)	5,147
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,125
9. Pacific (AK, CA, HI, OR, WA)	8,525

We intend to update these numbers in the FY 2014 final rule based on the latest available cost report data.

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, 5,000 discharges would be the minimum criterion for all hospitals under this proposed rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2013, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2011 (based on a combination of FY 2010 and FY 2011 cost report data as explained earlier in this section).

C. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. Section 1886(d)(12) of the Act sets forth the qualifying criteria for a qualifying low-volume hospital and the methodology for determining the low-volume hospital payment adjustment.

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 by expanding the definition of a low-volume hospital and modifying the methodology for determining the payment adjustment for hospitals meeting the definition. Therefore, prior to the enactment of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) on January 2, 2013, beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment requirements would have reverted to the statutory requirements under section 1886(d)(12) of the Act that were in effect prior to FY 2011. Section 605 of the ATRA extended for an additional year, through FY 2013, the temporary changes in the low-volume hospital definition and methodology for determining the payment adjustment made by the Affordable Care Act for FYs 2011 and 2012. Beginning with FY 2014, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and the ATRA. In section V.D.3. of this preamble, we discuss the proposed low-volume hospital payment adjustment policies for FY 2014.

a. Original Implementation of the Low-Volume Hospital Payment Adjustment

Section 1886(d)(12) of the Act, as added by section 406(a) of Public Law

108–173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is ''[i]n addition to any payment calculated under this section.'' Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

Section 1886(d)(12)(C)(i) of the Act defined a low-volume hospital as ''a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and has less than 800 discharges during the fiscal year.'' Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' means ''an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A.'' Therefore, the term ''discharge'' refers to total discharges, regardless of payer (that is, not only Medicare discharges). Furthermore, under section 406(a) of Public Law 108–173, which initially added subparagraph (12) to section 1886(d) of the Act, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between ''the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.'' The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume hospital payment adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume hospital payment adjustment implemented in FY 2005. Therefore, the low-volume hospital payment adjustment of an additional 25 percent continued to be provided for qualifying hospitals with less than 200 discharges.

b. Affordable Care Act Provisions for FYs 2011 and 2012

For FYs 2011 and 2012, sections 3125 and 10314 of the Affordable Care Act expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition. Specifically, those provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to specify that, for FYs 2011 and 2012, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year. In addition, section 1886(d)(12)(D) of the Act, as added 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 Part A in the fiscal year to zero percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.''

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we revised the regulations at 42 CFR 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals made by sections 3125 and 10314 of the Affordable Care Act. In addition, we defined, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1), and clarified the existing regulations to indicate that a hospital must continue to qualify as a low-volume hospital in order to receive the payment adjustment in that year (that is, it is not based on a one-time qualification). Furthermore, in that same final rule, we discussed the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2011 (75 FR 50240). For the second year of the changes to the low-volume hospital payment adjustment provided for by section 3125 and 10314 of the Affordable Care Act (that is, FY 2012), consistent with the regulations at § 412.101(b)(2)(ii), in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51677 through 51680), we updated the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase). Under § 412.101(b)(2)(ii), for FYs 2011 and 2012, 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 hospital payment adjustment in the current year. In that same final rule, we established that, for FY 2012, qualifying low-volume hospitals and their payment adjustment are determined using Medicare discharge data from the March 2011 update of the FY 2010 MedPAR file, as these data were the most recent data available at that time. In addition, we noted that eligibility for the low-volume hospital payment adjustment for FY 2012 was also dependent upon meeting (if the hospital was qualifying for the low-volume hospital payment adjustment for the first time in FY 2012), or continuing to meet (if the hospital qualified in FY 2011), the mileage criterion specified at § 412.101(b)(2)(ii). Furthermore, we established a procedure for a hospital to request low-volume hospital status for FY 2012 (which was consistent with the process we employed for the low-volume hospital payment adjustment for FY 2011).

2. Provisions of the ATRA for FY 2013

a. Background

Section 605 of the ATRA amended sections 1886(d)(12)(B), (C)(i), and (D) of the Act to extend, for FY 2013, the temporary changes in the low-volume hospital payment adjustment policy provided for in FYs 2011 and 2012 by the Affordable Care Act. As we have noted previously, prior to the enactment of section 605 of the ATRA, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology would have reverted to the policy established under statutory requirements that were in effect prior to the amendments made by the Affordable Care Act.

Prior to the enactment of the ATRA, in the FY 2013 IPPS/LTCH PPS final

rule (77 FR 53406 through 53409), we discussed the low-volume hospital payment adjustment for FY 2013 and subsequent fiscal years. Specifically, we discussed that in accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology would revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, we explained, as specified under the existing regulations at § 412.101, effective for FY 2013 and subsequent years, that in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 total discharges, including both Medicare and non-Medicare discharges) during the fiscal year. We also established a procedure for hospitals to request low-volume hospital status for FY 2013 (which was consistent with our previously established procedures for FYs 2011 and 2012).

In a **Federal Register** notice published on March 7, 2013 (78 FR 14689) (hereinafter referred to as the FY 2013 IPPS notice), we announced the extension of the Affordable Care Act amendments to the low-volume hospital payment adjustment requirements under section 1886(d)(12) of the Act for FY 2013 pursuant to section 605 of the ATRA. The applicable low-volume hospital percentage increase provided for by the provisions of the Affordable Care Act and the ATRA 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.

In the FY 2013 IPPS notice (78 FR 14689 through 14694), to implement the extension of the temporary change in the low-volume hospital payment adjustment policy for FY 2013 provided for by the ATRA, we updated the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase). Consistent with our implementation of the low-volume hospital payment adjustment policy for FYs 2011 and 2012 as set forth at existing § 412.101(b)(2)(ii), we established that, for FY 2013, qualifying low-volume hospitals and their payment adjustments are determined using Medicare discharge data from the March 2012 update of the FY 2011 MedPAR file, as these data were the most recent data available at the time of the development of the FY 2013 payment rates and factors established in the FY 2013 IPPS/LTCH PPS final rule. In addition, we noted that eligibility for the low-volume hospital payment adjustment for FY 2013 is also dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2012), or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2012), the mileage criterion specified at existing § 412.101(b)(2)(ii). We also established a procedure for a hospital to request low-volume hospital status for FY 2013 (which is consistent with the process for the low-volume hospital payment adjustment for FYs 2011 and 2012). Furthermore, we noted our intent to make conforming changes to the regulations text at § 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals in accordance with the amendments made by section 605 of the ATRA in future rulemaking. (We refer readers to the FY 2013 IPPS notice (78 FR 14689 through 14694) for additional information on the extension of the Affordable Care Act amendments to the low-volume hospital payment adjustment requirements under section 1886(d)(12) of the Act through FY 2013 in accordance with section 605 of the ATRA.)

b. Proposed Conforming Regulatory Changes

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we amended the regulations at § 412.101 to specify that, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology reverted to the policy established under statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. In this proposed rule, we are proposing to make 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 2013 in accordance with section 605 of the ATRA, as announced in the FY 2013 IPPS notice (as discussed above). Specifically, we are proposing to revise paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2), and (d). Under these proposed changes to § 412.101, beginning with FY 2014, consistent with section 1886(d)(12) of the Act, as amended, the low-volume hospital qualifying criteria and payment adjustment methodology would revert to that which was in effect prior to the amendments made by the Affordable Care Act and the ATRA (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010).

3. Proposed Low-Volume Hospital Definition and Payment Adjustment for FY 2014 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, as amended, beginning with FY 2014, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and the ATRA. Therefore, consistent with section 1886(d)(12) of the Act, as amended, under the proposed conforming changes to § 412.101(b)(2), effective for FY 2014 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. Under our existing policy, effective for FY 2014 and subsequent years, qualifying hospitals would receive the low-volume hospital payment adjustment of an additional 25 percent for discharges occurring during the fiscal year.

As described above, for FYs 2005 through 2010 and FY 2014 and subsequent fiscal years, the discharge determination would be made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume hospital payment adjustment in the current year (proposed § 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011, 2012, and 2013, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years. In addition to a discharge criterion, the eligibility for the low-volume hospital payment adjustment also would be dependent upon the hospital meeting the mileage criterion

specified at proposed § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2014 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital.

For FY 2014, we would continue to use the established process for requesting and obtaining the low-volume hospital payment adjustment. That is, in order to receive a low-volume hospital payment adjustment under § 412.101, a hospital must notify and provide documentation to its fiscal intermediary or MAC that it meets the discharge and distance requirements. The fiscal intermediary or MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment. The fiscal intermediary or MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional 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).)

Consistent with our previously established procedure, for FY 2014, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2013, in order for the 25-percent low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2013 (through September 30, 2014). If a hospital's request for low-volume hospital status for FY 2014 is received after September 1, 2013, and if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25-percent low-volume hospital payment adjustment to determine the payment for the hospital's FY 2014 discharges, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume hospital status determination.

As we discussed in section V.C.2.b. of the preamble of this proposed rule, we are proposing to make conforming changes to the regulatory 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 2013 made by section 605 of the ATRA. We are proposing changes to § 412.101 to conform the regulations to the statutory requirements that, beginning with FY 2014, the low-volume hospital qualifying criteria and payment adjustment methodology revert to that which was in effect prior to the amendments made by the Affordable Care Act and the ATRA (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010). Therefore, the low-volume hospital payment adjustment policy in effect prior for FYs 2005 through 2010 would apply for FY 2014 and subsequent years.

D. Indirect Medical Education (IME) Payment Adjustment (§ 412.105)

1. IME Adjustment Factor for FY 2014

Under the IPPS, an additional payment amount is made to hospitals that have 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) of the Act states that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2014, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2014 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident to bed ratio.

2. Other Proposed Policy Changes Affecting GME

In sections IV.J. of the preamble of this proposed rule, we present other proposed policy changes relating to GME payment. We refer readers to that section of the preamble of this proposed rule where we present the proposed policies.

E. 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. Counting of Patient Days Associated With Patients Enrolled in Medicare Advantage Plans in the Medicare and Medicaid Fractions of the Disproportionate Patient Percentage (DPP) Calculation

The regulation at 42 CFR 422.2 defines Medicare Advantage (MA) plan to mean ''health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan . . . .'' Generally, each MA plan must at least provide coverage of all services that are covered by Medicare Part A and Part B, but also may provide for Medicare Part D benefits and/or additional supplemental benefits. However, certain items and services, such as hospice benefits, continue to be covered under Medicare fee-for-service (FFS). We note that, under § 422.50 of the regulations, an individual is eligible to elect an MA plan if he or she is entitled to Medicare Part A and enrolled in Medicare Part B. Dual eligible beneficiaries (individuals entitled to Medicare and eligible for Medicaid) also may choose to enroll in a MA plan, and, as an additional supplemental benefit, the MA plan may pay for Medicare cost-sharing not covered by Medicaid.

In the FY 2004 IPPS proposed rule (68 FR 27208) in response to questions about whether the patient days associated with patients enrolled in a Medicare + Choice (M+C) plan [now Medicare Advantage (MA) plan under Medicare Part C] should be counted in the Medicare fraction or the Medicaid fraction of the disproportionate patient percentage (DPP) calculation, we proposed that once a beneficiary enrolls in an M+C plan, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DPP. Instead, those patient days would be included in the numerator of the Medicaid fraction, if the patient also were eligible for Medicaid. In the FY 2004 IPPS final rule (68 FR 45422), we did not respond to public comments on this proposal, due to the volume and nature of the public comments we received, and we indicated that we would address those comments later in a separate document. In the FY 2005 IPPS proposed rule (69 FR 28286), we stated that we planned to address the FY 2004 comments regarding M+C days in the IPPS final rule for FY 2005. In the FY 2005 IPPS final rule (69 FR 49099), we determined that, under § 412.106(b)(2)(i) of the regulations, MA patient days should be counted in the Medicare fraction of the DPP calculation. We explained that, even where Medicare beneficiaries elect Medicare Part C coverage, they are still entitled to benefits under Medicare Part A. Therefore, we noted that if a Medicare M+C beneficiary is also an SSI recipient, the patient days for that beneficiary will be included in the numerator of the Medicare fraction (as well as in the denominator) and not in the numerator of the Medicaid fraction. We note that, despite our explicit statement in the final rule that the regulations also would be revised, due to a clerical error, the corresponding regulation at § 412.106(b)(2)(i) was not amended to explicitly reflect this policy until 2007 (72 FR 47384).

On November 15, 2012, in a ruling in the case of *Allina Health Services, et al.,* v. *Sebelius (Allina),* the Federal District Court for the District of Columbia (the court) held that the final policy of putting MA patient days in the Medicare fraction adopted in the FY 2005 IPPS final rule was not a logical outgrowth of the FY 2004 IPPS proposed rule. The court held that interested parties had not been put on notice that the Secretary might adopt a final policy of counting the days in the Medicare fraction and were not provided an adequate further opportunity for public comment.

We continue to believe that individuals enrolled in MA plans are ''entitled to benefits under part A'' as the phrase is used in the DSH provisions at section 1886(d)(5)(F)(vi)(I) of the Act. Section 226(a) of the Act provides that an individual is automatically ''entitled'' to Medicare Part A when the person reaches age 65 or becomes disabled, provided that the individual is entitled to Social Security benefits under section 202 of the Act. Beneficiaries who are enrolled in MA plans provided under Medicare Part C continue to meet all of the statutory criteria for entitlement to Medicare Part A benefits under section 226 of the Act. First, in order to enroll in Medicare Part C, a beneficiary must be ''entitled to benefits under Part A and enrolled under Part B'' (section 1852(a)(1)(B)(i) of the Act). There is nothing in the Act that suggests that beneficiaries who enroll in a Medicare Part C plan forfeit their entitlement to Medicare Part A benefits. Second, once a beneficiary enrolls in Medicare Part C, the MA plan must provide the beneficiary with the benefits to which he or she is entitled under Medicare Part A, even though it may also provide for additional supplemental benefits (section 1852(a)(1)(A) of the Act). Third, under certain circumstances, Medicare Part A pays for care furnished to patients enrolled in Medicare Part C plans. For example, if, during the course of the year, the scope of benefits provided under Medicare Part A expands beyond a certain cost threshold due to Congressional action or a national coverage determination, Medicare Part A will pay the provider for the cost of those services directly (section 1852(a)(5) of the Act). Similarly, Medicare Part A also pays for federally qualified health center services and hospice care furnished to MA patients (section 1853(a)(4) and (h)(2) of the Act, respectively). Thus, we continue to believe that a patient enrolled in an MA plan remains entitled to benefits under Medicare Part A, and should be counted in the Medicare fraction of the DPP, and not the Medicaid fraction.

We also believe that our policy of counting patients enrolled in MA plans in the Medicare fraction was a logical outgrowth of the FY 2004 IPPS proposed rule, and, accordingly, have filed an appeal in the *Allina* case. However, in an abundance of caution and for the reasons discussed above, in this proposed rule, we are proposing to readopt the policy of counting the days of patients enrolled in MA plans in the Medicare fraction of the DPP. We are seeking public comments from interested parties that may support or oppose the proposal to include the MA patient days in the Medicare fraction of the DPP calculation for FY 2014 and subsequent years. We will evaluate these public comments and consider whether a further change in policy is warranted, and will include our final determination in the FY 2014 IPPS final rule. We are not proposing any change to the regulation text at this time, because the current text reflects the policy being proposed.

3. New Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) Under Section 3133 of the Affordable Care Act (§ 412.106)

a. General Discussion and Legislative Change

Section 3133 of the Patient Protection and Affordable Care Act (PPACA), as amended by section 10316 of PPACA 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 proposed rule, we will refer to these

provisions collectively as Section 3133 of the Affordable Care Act.

Currently, Medicare DSH adjustment 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 for discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(II) of the Act, the so-called Pickle hospitals. Pursuant to new section 1886(r), Pickle hospitals would receive 25 percent of the 35 percent add-on adjustment for which they would otherwise qualify under section 1886(d)(5)(F)(i)(II). 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, will become 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 will be 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.

Specifically, as provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for ''fiscal year 2014 and each subsequent fiscal year,'' a ''subsection (d) hospital'' that would otherwise receive a ''disproportionate share hospital payment . . . made under subsection (d)(5)(F)'' will receive 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 disproportionate share 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 payment, section 1886(r)(2) of the Act provides that, for fiscal year 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 subsection (d)(5)(F) if this subsection did not apply'' and ''the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1)'' 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 then Director of the Congressional Budget Office to the Speaker of the House. A link to this letter is included in section V.E.3.d.2. of the preamble of this proposed rule.

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 ''who are uninsured in the most recent period for which data is available (as so estimated and certified) minus 0.2 percentage points for FYs 2018 and 2019.'' Thus, for FY 2018 and subsequent years, the statute provides some greater flexibility in the choice of the data sources to be used in the estimate of the change in the percent of the uninsured.

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 this subsection.'' 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 states that this provision is effective for ''fiscal year 2014 and each subsequent fiscal year.'' In this proposed rule, we set forth our proposals for implementing the required changes to the DSH payment methodology. We note that, because section 1886 (r) 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 paragraph (2),'' or of ''any period selected by the Secretary'' for the purpose of determining those factors. Therefore, there can be 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

As indicated above, the new payment methodology applies to ''subsection (d) hospitals'' that would otherwise receive a ''disproportionate share payment . . . made under subsection (d)(5)(F).'' Therefore, eligibility for empirically justified Medicare DSH payments is unchanged under this new provision. Consistent with the law, hospitals must receive empirically justified Medicare DSH payments in FY 2014 or a subsequent year to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, ''[i]n addition to the payment made to a subsection (d) hospital under paragraph (1), . . . the Secretary shall pay to *such subsection (d) hospital* an additional amount . . .'' (Emphasis supplied.) Because paragraph (1) refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) is, therefore, limited to hospitals that receive empirically justified Medicare DSH payments pursuant to section 1886(r)(1) of the Act for FY 2014 and subsequent years.

In this proposed rule, we are proposing that hospitals that are not eligible to receive empirically justified Medicare DSH payments in FY 2014 and subsequent years would not receive uncompensated care payments for those respective years. We also are proposing to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for FY 2014 or the applicable year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status on the cost report for that payment year. (We discuss these proposals in more detail below.)

In the course of developing these proposed policies for implementing the provision of section 1886(r) of the Act, we considered whether several specific classes of hospitals are included within the scope of the statutory provision. In particular, we considered whether the provision applies to (1) hospitals in the Commonwealth of Puerto Rico, (2) hospitals in the State of Maryland paid under a waiver as provided in section 1814(b) of the Act, (3) sole community hospitals (SCHs), (4) hospitals participating in the Bundled Payments for Care Improvement Initiative developed by the Center for Medicare and Medicaid Innovation (Innovation Center), and (5) hospitals participating in the Rural Community Hospital demonstration. We discuss each of these specific classes of hospitals below.

(1) Puerto Rico Hospitals

Under section 1886(d)(9)(A) of the Act, Puerto Rico hospitals subject to the IPPS are not ''subsection (d) hospitals,'' but rather constitute a distinct class of ''subsection (d) Puerto Rico hospitals.'' However, section 1886(d)(9)(D)(iii) of the Act specifies that subparagraph (d)(5)(F) (the provision governing the current DSH payment methodology) ''shall apply to subsection (d) Puerto Rico hospitals . . . in the same manner and to the extent as [it applies] to subsection (d) hospitals.'' While the new section 1886(r) of the Act does not specifically address whether the methodology established there applies to ''subsection (d) Puerto Rico hospitals,'' section 3133 of the Affordable Care Act does make a revision to section 1886(d)(5)(F)(i) of the Act that is crucial for determining the eligibility of Puerto Rico hospitals for empirically justified Medicare DSH payments and uncompensated care payments under the new provision. Specifically, section 3133 of the Affordable Care Act amended section 1886(d)(5)(F)(i) of the Act to provide that this section is ''[s]ubject to subsection (r).'' One effect of this amendment is to provide that all hospitals subject to section 1886(d)(5)(F)(i) of the Act, including ''subsection (d) Puerto Rico hospitals,'' also are subject to the new payment methodology established in section 1886(r) of the Act.

In this proposed rule, we are proposing that subsection (d) Puerto Rico hospitals that are eligible for DSH payments also would be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology.

We are inviting public comments on this proposal.

(2) Hospitals Paid Under a Waiver Under Section 1814(b) of the Act

Under section 1814(b) of the Act, hospitals in the State of Maryland are subject to a waiver from the Medicare payment methodologies under which they would otherwise be paid. We have taken the position in other contexts, for example, for purposes of EHR incentive payments (75 FR 44448), that Maryland acute care hospitals remain subsection (d) hospitals. This is because these hospitals are ''located in one of the fifty States or the District of Columbia'' (as provided in the definition of subsection (d) hospitals) and do not meet the definitions of the hospitals that are specifically excluded from that category, such as cancer hospitals and psychiatric hospitals. However, section 1886(r) of the Act applies to hospitals that are both subsection (d) hospitals and hospitals that would otherwise receive a disproportionate share payment made under the previous DSH payment methodology. Because Maryland waiver hospitals are paid under section 1814(b)(3) of the Act and not under section 1886(d)(5)(F) of the Act, they are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology of section 1886(r) of the Act.

(3) Sole Community Hospitals (SCHs)

SCHs are paid based on their hospital-specific rate from certain specified base years or the IPPS Federal rate, whichever yields the greatest aggregate payment for the hospital's cost reporting period. Payments based on the Federal rate are based on the IPPS standardized amount and include all applicable IPPS add-on payments, such as outliers, DSH, and IME, while payments based on the hospital-specific rate have no add-on payments. For each cost reporting period, the fiscal intermediary/MAC determines which of the payment options will yield the highest aggregate payment. Interim payments are automatically made on a claim-by-claim basis at the highest rate using the best data available at the time the fiscal intermediary/MAC makes the payment determination for each discharge. However, it may not be possible for the fiscal intermediary/MAC to determine in advance precisely which of the rates will yield the highest aggregate payment by year's end. In many instances, it is not possible to forecast outlier payments or the final amount of the DSH payment adjustment or the IME adjustment until cost report settlement. As noted above, these adjustment amounts are applicable only to payments based on the Federal rate and not to payments based on the hospital-specific rate. The fiscal intermediary/MAC makes a final adjustment at cost report settlement after it determines precisely which of the payment rates would yield the highest aggregate payment to the hospital for its cost reporting period. This payment methodology makes SCHs unique as they can change on a yearly basis from receiving hospital-specific rate payments to receiving Federal rate payments, or vice versa.

In order to implement the provisions of section 1886(r) of the Act, we are proposing to continue to determine interim payments for SCHs 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. We also are proposing that SCHs that receive interim empirically justified DSH payments in a fiscal year would receive interim uncompensated care payments that fiscal year, subject as well to settlement through the cost report. Final eligibility determinations would be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments would be adjusted accordingly. We are thus proposing to follow the same processes of interim and final payments for SCHs that we are proposing to follow for eligible IPPS DSH hospitals generally. (We discuss these processes in more detail below.)

As previously noted, under the SCH payment methodology, SCHs are paid the higher of the Federal rate or a hospital-specific payment rate. This payment methodology is defined under sections 1886(d)(5)(D)(i) and 1886(d)(1)(A)(iii) of the Act. Section 1886(d)(3) specifically provides that SCH payments are to be made on a per-discharge basis. Accordingly, as we also note below, we are proposing that the uncompensated care payments would not be accounted for in determining whether an SCH is paid the higher of the Federal rate or the hospital-specific rate. This is because the uncompensated care payments are not discharge-driven payments, but rather are payments made on the basis of a hospital's overall share of uncompensated care during a payment year. The amount of a hospital's uncompensated care payments for a year is not directly affected by the number of the hospital's discharges for the year. Therefore, we do not believe that uncompensated care payments should be taken into account in a comparison based on discharge driven hospital-specific and Federal rate payments. Furthermore, as we propose later in this rule, we intend to make interim uncompensated care payments on a periodic basis rather than a per discharge basis in order to create more predictability for hospitals and to increase administrative efficiency. To the extent the payments are intended to reflect the relative amount of uncompensated care furnished by the hospital, it is both reasonable and appropriate to view this payment as an amount for the year, which in the interests of predictability and consistency is made periodically through interim payments.

We are inviting public comments on all of these proposals affecting SCHs.

(4) Hospitals Participating in the Bundled Payments for Care Improvement Initiative

IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative receive a payment that links multiple services furnished to a patient during an episode of care. We have stated in previous rulemaking that those hospitals continue to be paid under the IPPS (77 FR 53342). Hospitals that elect to participate in the initiative can still receive DSH payments while participating in the initiative, if they otherwise meet the requirements for receiving such payments.

In this proposed rule, we are proposing to apply the new DSH payment methodology to the hospitals in this initiative, so that eligible hospitals would receive empirically justified DSH payments and uncompensated care payments.

We are inviting public comments on this proposal.

(5) Hospitals Participating in the Rural Community Hospital Demonstration

Section 410A of the Medicare Modernization Act established the Rural Community Hospital Demonstration Program. After the initial 5-year period, the demonstration was extended for an additional 5-year period by sections 3123 and 10313 of the Affordable Care Act. There are 23 hospitals currently participating in the demonstration. Under the payment methodology provided in section 410A, participating hospitals receive payment for Medicare inpatient services on the basis of a cost methodology. Specifically, for discharges occurring in the hospitals' first cost reporting period of the initial 5-year demonstration or the first cost reporting period of the 5-year extension, they receive payments for the reasonable cost of providing such services. For discharges occurring in subsequent cost reporting periods during the applicable 5-year demonstration period, hospitals receive the lesser of the current year's reasonable cost amount, or the previous year's amount updated by the percentage increase in the IPPS market basket (the target amount). (We refer readers to section V.K. of the preamble of this proposed rule for further information on the demonstration.) The instructions (CR 5020 (April 14, 2006) and CR 7505 (July 22, 2011)) for the demonstration require that the fiscal intermediary/MAC not pay Medicare DSH payments in addition to the amount received under the cost-based payment methodology. Although the amounts that would otherwise be paid for Medicare DSH payments (absent the demonstration) are calculated and identified on the hospital cost report for statistical and research purposes, as in the case of Maryland waiver hospitals, hospitals in this demonstration do not receive a separate or identifiable DSH payment.

Because hospitals participating in the Rural Community Hospital Demonstration do not receive DSH payments, these hospitals are also excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology.

c. Empirically Justified Medicare DSH Payments

As we have discussed above, the statute requires CMS to pay 25 percent of the ''amount of disproportionate share hospital payment that would otherwise be made under subsection (d)(5)(F) to a subsection (d) hospital.'' Currently, we have a system for interim payment and final settlement of DSH payments made under section 1886(d)(5)(F). Specifically, interim payments are made for each claim based on the best available data concerning each hospital's eligibility for DSH payments and the appropriate level of such payments. Final eligibility for Medicare DSH payments and the final amount of such payments for eligible hospitals are determined at the time of cost report settlement. 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 do not believe that it is necessary to develop and propose any new operational mechanisms for making such payments.

Therefore, we are proposing to implement this provision simply by revising the claims payment methodologies to adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We will also make 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 will provide more detailed operational instructions and cost report instructions following issuance of the final rule.

We are proposing to implement this provision by adding a new paragraph (f) under the regulations at 42 CFR 412.106. This proposed new paragraph

provides for reducing Medicare DSH payments by 75 percent beginning in FY 2014.

We are inviting public comments on this proposal.

d. Uncompensated Care Payments

As we have discussed above, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the new 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 a base of 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 proposed data sources and methodologies for computing each of these factors.

Before we begin to discuss these data sources and methodologies, it is necessary to discuss the timing and manner for determining the eligibility of hospitals for uncompensated care payments. The statute provides that subsection (d) hospitals that receive a payment under section 1886(d)(5)(F) of the Act are eligible to receive a payment under section 1886(r)(2) of the Act. Specifically, section 1886(r)(2) of the Act states that, ''[i]n addition to the payment made to a subsection (d) hospital under paragraph (1) . . . the Secretary shall pay to such subsection (d) hospitals an additional amount. . . .'' Therefore, because paragraph (1) refers to empirically justified Medicare DSH payments, the additional payment for FY 2014 and subsequent years is limited to hospitals that receive empirically justified Medicare DSH payments for the respective year. However, as we have discussed above, we currently have a system for interim payment and final settlement of DSH payments. Specifically, interim payments are made for each claim based on the best available data concerning each hospital's eligibility for DSH payments and the appropriate level of such payments. Final determination of eligibility for Medicare DSH payments and the final amount of such payments for eligible hospitals are determined at the time of cost report settlement.

As we describe above, because section 1886(r)(1) of the Act does not revise the criteria governing eligibility for DSH payments or the underlying payment methodology, we do not believe that it is necessary to develop and propose any new operational mechanisms for making such payments and would thus continue using the existing system of interim eligibility and payment determination with final cost report settlement for the empirically justified Medicare DSH payments. We are proposing to adopt a similar system of interim eligibility and payment determination with final cost report settlement for purposes of uncompensated care payments. We discuss the specific operational details of this system in section V.E.3.f. of this preamble.

We are inviting public comments on these proposals.

(1) Proposed Methodology To Calculate Factor 1

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 subsection (d)(5)(F) if this subsection 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 paragraph (1) for such a 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 if the reduction to the Medicare DSH payment by 75 percent under section 1886(r)(1) of the Act did not apply for such fiscal year. In other words, section 1886(r)(2)(A)(i) of the Act represents an estimate of the full Medicare DSH payment amount under section 1886(d)(5)(F) prior to the 75-percent reduction, for FY 2014 and subsequent years. This subparagraph specifies that, for each fiscal year to which the provision applies, such amount is to be ''estimated by the Secretary.'' 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, the statute gives CMS 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 FY 2014 and subsequent years, taking into account the application of the 75 percent reduction to the DSH payment amounts prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act gives CMS 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 FY 2014 and subsequent years, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for FY 2014 and subsequent years, which takes into account the requirement to reduce Medicare DSH payments by 75 percent. 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 FY 2014 and subsequent years.

In order to determine Factor 1 in the uncompensated care payment formula, we are proposing to develop final estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1) prior to each fiscal year to which the new provision applies. We believe this will create some level of predictability and finality for hospitals eligible for these payments, in addition to being administratively efficient. Specifically, in order to determine the two elements of Factor 1 (Medicare DSH payments prior to the application of the 75 percent reduction, and empirically justified Medicare DSH payments after application of the 75 percent reduction), we are proposing to use the most recently available projections of Medicare DSH payments for FY 2014 and each subsequent year, as calculated by CMS' Office of the Actuary. The Office of the Actuary projects Medicare DSH payments on a biannual basis, typically in February of each year (based on data from December of the previous year) as part of the President's Budget, and in July (based on data from June) as part of the Midsession Review. The estimates are based on 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.

Therefore, for the Office of the Actuary's February 2013 estimate, the data are based on the December 2012 update of the Medicare Hospital Cost Report Information System (HCRIS) and

the FY 2013 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2013 IPPS/LTCH PPS final rule. For the July 2013 estimate, we anticipate that the data will be based on the March 2013 update of the Medicare Hospital Cost Report data and this proposed rule's IPPS Impact file, published in conjunction with this proposed rule. For purposes of this proposed rule, we are using the February 2013 Medicare DSH estimates to calculate Factor 1 and to model the proposed impact of this provision. If our proposal to use the Office of the Actuary's projections for Factor 1 is finalized, we would use the July 2013 Medicare DSH estimates to determine Factor 1 for the FY 2014 IPPS/LTCH PPS final rule.

In addition, because we are proposing to exclude sole community hospitals paid under their hospital specific payment rate from the application of section 1886(r) of the Act, we are also proposing to exclude these hospitals from our Medicare DSH estimate. Similarly, because Maryland hospitals and hospitals participating in the Rural Community Hospital Demonstration do not receive DSH payments, we also exclude these hospitals from our Medicare DSH estimate.

Using the data sources discussed above, the Office of the Actuary uses the most recently submitted Medicare cost report data to identify current Medicare DSH payments and the most recent DSH payment adjustments provided in the IPPS Impact File, and 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 2013 Office of the Actuary estimate for Medicare DSH payments for FY 2014, without regard to the application of section 1886(r)(1) of the Act, is 12.338 billion. This estimate excludes Maryland hospitals, sole community hospitals paid under their hospital specific payment rate and hospitals participating in the Rural Community Hospital Demonstration as discussed above. Therefore, based on this estimate, the estimate for empirically justified Medicare DSH payments for FY 2014, with the application of section 1886(r)(1) of the Act, is $3.084 billion (25 percent of the total amount estimated). Under our proposal, Factor 1 is the difference of these two estimates of the Office of the Actuary. Therefore, for the purpose of modeling Factor 1, we calculate Factor 1 to be $9.2535 billion.

We also are proposing to develop and use the estimates necessary for Factor 1 on a purely prospective basis. We are proposing to use the Actuary's most recent February Medicare DSH estimates each year to calculate Factor 1 and to model the impact of this provision for the IPPS/LTCH PPS proposed rule. Similarly, we are proposing to use the Actuary's most recent July Medicare DSH estimates to determine Factor 1 for the IPPS/LTCH PPS final rule each year. In other words, we would not revise or update our estimates after we know the final Medicare DSH payments for FY 2014 and subsequent years. As we discussed earlier, 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. Because the statute provides that CMS use estimates in order to determine Factor 1 each year, we believe that applying our best estimates prospectively would be most conducive to administrative efficiency, finality, and predictability in payments.

We are inviting public comments on all the elements of this proposed methodology to calculate Factor 1.

We are proposing to add a new paragraph (g)(1)(i) under § 412.106 of our regulations to define the methodology for calculating Factor 1.

(2) Proposed Methodology To Calculate Factor 2

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: ''For each of fiscal years 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 Patient Protection and 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 is available (as so calculated), minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.''

Section 1886(r)(2)(B) of the Act establishes, as Factor 2 in the uncompensated care payment formula, the percent change in uninsurance, based on a comparison of the percent of individuals under 65 without insurance in 2013 to the percent of such individuals without insurance in the most recent period for which we have data, minus 0.1 percentage points for FY 2014 and 0.2 percentage points 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 Patient Protection and 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 . . .'' appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. (Emphasis supplied.) 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). (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 CBO letter to the Speaker of the House, the CBO provides two estimates of the ''post-policy uninsured population.'' The first estimate is of the ''Insured Share of the Nonelderly Population Including All Residents'' (which is 82 percent) and the second estimate is of the ''Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants'' (83 percent). We are proposing to use the first estimate that includes all residents, including unauthorized immigrants. 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 65.

In addition, we believe that this estimate would more fully reflect the levels of uninsurance in the United States that influence uncompensated care for hospitals. Therefore, using this estimate would seem more consistent with the statutory requirement of establishing a payment for uncompensated care. For these reasons, we are proposing to use the estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' for 2013 to calculate the baseline percentage of individuals under age 65 without insurance.

We are inviting public comments on this proposal.

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 2013,'' we are proposing to use the CBO insurance rate figure and subtract that amount from 100 percent (i.e., the total population, without regard to insurance status) to estimate the 2013 baseline percentage of individuals without insurance. In its March 20, 2010 letter, the CBO reported its estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' as 82 percent. Therefore, we are proposing that, for FYs 2014–2017, our estimate of the uninsurance percentage for 2013 would be 18 percent. As provided for in the CBO March 20, 2010 letter, the CBO estimate for insurance for the nonelderly (under age of 65) population only includes residents of the 50 States and the District of Columbia, and the count of uninsured people includes unauthorized immigrants, as well as people who are eligible for, but not enrolled in, Medicaid. We note that, although we are proposing that acute care hospitals located in Puerto Rico that receive DSH payments will be eligible to receive payments under section 1886(r) of the Act, this estimate for insurance does not account for residents in Puerto Rico. We believe that the impact of the exclusion of Puerto Rico from the insurance estimate is negligible.

We are inviting public comments on this proposal.

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 is available (as so calculated).'' We are proposing to use the same data source, CBO estimates, to calculate this percent of individuals without insurance. 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 for 2014 ''as *so* calculated.'' (Emphasis supplied.) The phrase ''as so calculated'' in the latter section can be reasonably interpreted to require the calculation to similarly be based on CBO estimates. In addition, we believe that it is preferable from a statistical point of view to calculate a percent change in insurance over time using a consistent data source. Furthermore, rather than using the estimates included in the March 20, 2010 CBO letter, we believe it is appropriate to use more recent CBO estimates of the percent of individuals with insurance. The more recent CBO projections take into account changes in the environment that can impact insurance rates, such as more recent economic conditions and the Supreme Court's decision in *National Federation of Independent Business.* v. *Sebelius,* ___ U.S. ___, 132 S. Ct. 2566 (2012), regarding Medicaid expansions authorized by the Affordable Care Act. Because the statute requires that we use ''the most recent period for which data is available'' to calculate the comparison percentage of individuals without insurance, we are proposing to use the most recent update (that is, the most recent update available at the time of rulemaking with respect to a particular fiscal year) to the percent of individuals with insurance provided by the CBO to calculate this comparison figure.

In addition, for FY 2014, we are proposing to use CBO's most recent estimate for the percent of individuals with insurance in 2014 for purposes of section 1886(r)(2)(B)(i)(II) because this is the year in which this provision is effective. This figure is used for Factor 2 and later applied to Factor 1, which is also based on an estimate for FY 2014. On February 5, 2013, the CBO released its annual *Budget and Economic Outlook.* The report included updated economic and budget projections that incorporated the effects of the legislation enacted prior to the start of the year, a revised economic forecast consistent with the budget projections, and other changes to CBO's estimates. (To view the report, we refer readers to the Web site at: *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900_ACAInsuranceCoverageEffects.pdf.*)

In this proposed rule, we are using the February 5, 2013, CBO health insurance estimates in order to calculate the percentage of individuals without insurance for 2014. As we did for the uninsurance percentage estimate for 2013 (based on the March 20, 2010 CBO letter discussed above), we are proposing to use the ''Insured Share of the Nonelderly Population Including All Residents'' to calculate the comparison of percentage of people without insurance for 2014. Consistent with the CBO estimate used to calculate the baseline uninsurance estimate, this estimate for insurance only includes residents of the 50 States and the District of Columbia, and the count of uninsured people includes unauthorized immigrants, as well as people who are eligible for, but not enrolled in, Medicaid. The CBO report projects that the ''Insured Share of the Nonelderly Population Including All Residents'' for 2014 will be 84 percent. Therefore, in the same manner that we calculated the uninsurance percentage for the baseline, we are proposing that the uninsurance percentage for 2014 would be 16 percent (i.e., 100 percent minus 84 percent) for the purpose of this proposed rule. If our proposal is finalized, and there is a more recent estimate of the percentage of individuals with insurance in 2014 by the CBO available for the FY 2014 IPPS/LTCH PPS final rule, we would use that estimate to calculate Factor 2. However, we would not adjust Factor 2 retroactively to account for estimates that become available after publication of the final rule.

Section 1886(r)(2)(B)(i) of the Act states that Factor 2 for FY 2014 is 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 without insurance in the baseline and in the most recent period for which we have data (minus 0.1 percentage points for FY 2014). Therefore, we are proposing that Factor 2 is 1 minus the percent change of the baseline percentage of individuals without insurance in 2013 (which is, for this proposed rule, 18 percent) and the most recent percentage of individuals without insurance for 2014 (which is, for this proposed rule, 16 percent) minus 0.1 percentage points.

Using the March 20, 2010 CBO projection for 2013 and the February 5, 2013 CBO projection of uninsurance for all residents for 2014, we are proposing to use the following computation for Factor 2 for FY 2014:

Percent of individuals without insurance for 2013: 18 percent

Percent of individuals without insurance for 2014: 16 percent

$1 - |[(0.16 - 0.18)/0.18]| = 1 - 0.111 = 0.889$ (88.9 percent)

0.889 (88.9 percent) − 0.001 (0.1 percentage points) = 0.888 (88.8 percent)
0.888 = Factor 2

Accordingly, we are proposing Factor 2 to be 88.8 percent for FY 2014. In conjunction with this proposal, we are therefore proposing that the amount available for uncompensated care payments for FY 2014 will be $8.217 billion (0.888 times our proposed Factor 1 estimate of $9.2535 billion). As we noted previously, our proposal for Factor 2 may be subject to change if more recent CBO estimates of the insurance rate for 2014 become available prior to the preparation of the final rule.

We are inviting public comment on our proposed methodology to calculate Factor 2.

In this proposed rule, we are proposing to add a new paragraph (g)(1)(ii) under § 412.106 of our regulations to define the methodology for calculating Factor 2.

(3) Proposed Methodology To Calculate Factor 3

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed above, 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 is available which is 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 this subsection 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 subsection (d) Puerto Rico hospital with the potential to receive DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive 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 years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, we must determine the following: (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 denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive DSH payments in the applicable FY); (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 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 alternative data is available, which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured.

In the course of considering how to determine Factor 3, we considered proposing to define the amount uncompensated care for a hospital as the uncompensated care costs of that hospital and considered potential data sources for those costs. In doing so, we first considered which costs should be included in the definition of ''uncompensated care costs.'' We examined the broad literature on uncompensated care and the concepts of uncompensated care used in various public and private programs. We also considered input from stakeholders and public comments in various forums, including the national provider call that we held in January 2013. Our review of the information from these sources indicated that there is some variation in how different States, provider organizations, and Federal programs define ''uncompensated care.'' However, a common theme of almost all these definitions is that they include both ''charity care'' and ''bad debt'' as constituents of ''uncompensated care.'' After considering the various factors that are included in different definitions of ''uncompensated care,'' we considered proposing to adopt a definition which incorporated those factors that are most commonly included within the term. Thus we considered proposing to define ''uncompensated care'' as the cost of charity care plus bad debt which includes the cost of non-Medicare bad debt and non-reimbursed Medicare bad debt. In turn, we also considered proposing to define ''charity care costs'' as the cost of care for patients that meet hospitals' individual criteria for charity care net of any partial payment received by the hospital from patients for that care, and to define ''non-Medicare bad debt costs'' as the cost of hospital care for non-Medicare patients that have the financial capacity to pay, but are unwilling to settle the claim. In addition, we considered proposing to define ''non-reimbursed Medicare bad debt costs'' as the amount of allowable coinsurance and deductible for Medicare patients from whom the hospital has sought to collect payment through reasonable collection efforts as described in § 413.89(e) of the Medicare regulations and not reimbursed by Medicare.

Charity care is most commonly defined as hospital care provided to individuals that meet certain financial eligibility criteria, for which the hospital does not expect to receive payment because of the individual's inability to pay. Definitions of charity care also regularly state that a patient must meet several guidelines for their care to qualify as charity care. These guidelines usually state that the patient must be uninsured, unqualified for a Federal program such as Medicaid, and/or fall under a certain Federal poverty line (FPL) standard. Some charity care is directed at insured individuals when insurance does not cover all the costs of their hospital care or when there are annual or lifetime limits. This definition also varies by hospital. Some hospitals may also seek payment from individuals who qualify for charity care as part of their financial assistance policies or to help offset the cost of that patient's hospital care. To the extent that hospitals receive payment from a patient that qualifies for charity care for hospital care provided, we believe that those payments should be subtracted from the costs of that care. In this way, the cost of charity care reflects the financial burden on the hospital, or, stated another way, the cost of charity care reflects only the uncompensated portion of the charity care.

The literature suggests that bad debt has been consistently defined as unreimbursed care for persons for which the hospital did not receive payment. The regulations at 42 CFR 413.89(b)(1) define Medicare bad debt as ''amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services.'' The regulations also specify that: '''accounts receivable' and 'notes receivable' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.'' Section 413.89(e) further specifies that under

Medicare ''bad debt must meet the following criteria to be allowable: (1) The debt must be related to covered services and derived from deductible and coinsurance amounts. (2) The provider must be able to establish that reasonable collection efforts were made. (3) The debt was actually uncollectible when claimed as worthless. (4) Sound business judgment established that there was no likelihood of recovery at any time in the future. We considered proposing to use the cost of non-Medicare and non-reimbursed Medicare bad debt (as reported on line 29 of the Worksheet S–10) as part of the proposed definition of ''uncompensated care.''

Some definitions of uncompensated care, including that used for calculating the Medicaid DSH hospital payment limit at 42 CFR 447.299(c)(16), also include the difference between the costs incurred by a hospital for services to Medicaid individuals and applicable revenues for these services. While we recognize in some cases, a hospital may receive revenues that do not fully cover those costs, we note that this is true for any patient population treated by a hospital regardless of insurance status. Hospitals negotiate contractual allowances with commercial payers, and it is possible that payment for some of these patients would be less than the costs of their care.

We emphasize, however, that we plan to monitor the potential effects of different definitions of uncompensated care on various measures designed to expand health insurance coverage under the Affordable Care Act, including Medicaid expansion.

Specifically, we wish to avoid creating a policy that would serve as a disincentive for States wishing to expand Medicaid. Using some of the data discussed in this proposed rule, we recognize it would be possible for hospitals in States that choose to expand Medicaid to receive lower uncompensated care payments because they are less likely to have uninsured patients than hospitals in a State that does not choose to expand Medicaid. In practice, because the available data sources (such as the Medicare cost report) for a given federal fiscal year are not available until some time after the end of that federal fiscal year, we believe that data to understand these effects will not be available until 2016 or later. However, we also note that hospitals in expansion States would receive full Medicaid reimbursement for many previously uninsured patients. So on balance, we believe both hospitals and States stand to benefit greatly from Medicaid expansion, regardless of the data used to determine Factor 3. However, if warranted, we may in the future reconsider how to define uncompensated care, such as to include differences between applicable Medicaid costs and revenues, or consider other definitions that would account for differences in State Medicaid coverage.

For purposes of selecting an appropriate data source for this possible definition of uncompensated care costs, we reviewed the literature and available data sources and determined that the Medicare cost report Worksheet S–10 could potentially provide the most complete data for Medicare hospitals. (We refer readers to the report ''Improvements to Medicare Disproportionate Share (DSH) Payments'' for a full discussion and evaluation of the available data sources. The report can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.) However, Worksheet S–10 is a relatively new data source that has been used for specific payment purposes only in relatively restricted ways (e.g., to provide a source of charity care charges in the computation of EHR incentive payments; 75 FR 44456.). Some stakeholders have expressed concern that hospitals have not had enough time to learn how to submit accurate and consistent data through this reporting mechanism. Other stakeholders have maintained that some instructions for Worksheet S–10 still require clarification in order to ensure standardized and consistent reporting by hospitals. We understand and appreciate the concerns of these stakeholders. At the same time, Worksheet S–10 is the only national data source that includes data for all Medicare hospitals and is designed to elicit data that are both accurate and consistent with the definition of uncompensated care costs that we considered proposing to use.

Charity care information is reported on Worksheet S–10, lines 20 through 23. On line 20, Column 3, hospitals report ''Total initial obligation of patients approved for charity care (at full charges excluding non-reimbursable cost centers) for the entire facility'' for both the insured and uninsured population. On Worksheet S–10, line 21, the charity care charges reported on line 20 are converted to charity care costs by multiplying the charity care charges by the cost-to-charge ratio (CCR) reported on line 1 of Worksheet S–10. Partial payment by patients for charity care is reported on line 22 of Worksheet S–10. Charity care costs are reported on line 23 of Worksheet S–10 as the difference between line 21 and 22. We could use ''Cost of Charity Care,'' line 23, Column 3 of Worksheet S–10 to identify a hospital's charity care costs, as part of a definition of ''uncompensated care.''

Bad debt information is reported on Worksheet S–10, lines 26 through 29. On Worksheet S–10, line 26 and line 27, a hospital reports its total bad debt expense and its Medicare reimbursed bad debt expense, respectively. On Worksheet S–10, line 28 represents the non-Medicare bad debt expense and non-reimbursed Medicare bad debt expense, the difference between lines 27 and 26. The cost of non-Medicare bad debt and non-reimbursed Medicare is reported on line 29 of the Worksheet S–10 as the product of the CCR and the non-Medicare and non-reimbursed Medicare bad debt expense reported on line 28. We could use the cost of non-Medicare bad debt and non-reimbursed Medicare that is reported on line 29 of the Worksheet S–10 to identify a hospital's bad debt costs, as part of a definition of ''uncompensated care.''

To summarize, we could use the sum of line 23, Column 3 of Worksheet S–10 and line 29 of Worksheet S–10 to estimate a hospital's uncompensated care cost. A hospital's individual uncompensated care cost based on this estimate would represent that hospital's numerator for Factor 3. The sum of the estimated uncompensated care costs for all the hospitals that we estimate would receive DSH payments (and thus the uncompensated care payment) for the fiscal year would represent the denominator of Factor 3.

In order to apply a definition of uncompensated care costs based upon information reported on the Worksheet S–10, it would be necessary to use the 2010/2011 cost reports, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. These are the most recently available full year of cost reports and the first cost reports with detailed uncompensated care data on the Worksheet S–10 that would be available for use in implementing the new methodology for uncompensated care payments for FY 2014. Concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use. Because of these concerns, we are not proposing to define of uncompensated care in a way that would require use of the Worksheet S–10 data.

We believe, however, that Worksheet S–10 of the Medicare Cost Report would otherwise be an appropriate data source to determine uncompensated care costs. In particular, we note that 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 that it is not unreasonable to expect information on the cost report to be used for payment purposes. Furthermore, hospitals attest to the accuracy and completeness of the information reported in the cost report at the time of submission. While we realize that hospitals may wish to have a more specific understanding of how this data will be used, we believe that the discussion in this proposed rule will help to increase their understanding and also inform our efforts to refine the cost report and cost report instructions so that hospitals may continue to gain experience in reporting accurate information. We also expect reporting on Worksheet S–10 to improve over time, particularly in the area of charity care which is already being used and audited for payment determinations related to the electronic health record incentive program, and will continue to monitor these data. Accordingly, we may proceed with a proposal to use data on the Worksheet S–10 to determine uncompensated care costs in the future, once hospitals are submitting accurate and consistent data through this reporting mechanism.

As we describe above, we are concerned about stakeholder input that the variations in the data reported on Worksheet S–10 of the Medicare cost report regarding uncompensated care may be due to hospitals' relative lack of experience reporting all of the data elements on that worksheet. A large number of stakeholders noted that there is considerable variation and numerous inconsistencies in how uncompensated care is calculated and reported in Worksheet S–10 and they point out that these inconsistencies can produce divergent results. Some went as far as noting that data from Worksheet S–10 is ''flawed'' and many suggested more precision in reporting instructions to help hospitals report data in a more consistent manner. We note that most of the data elements reported on Worksheet S–10 have been previously unused for payment purposes, with only some data elements recently being used for determining a hospital's electronic health record incentive payments, and these data elements have not been subject to audit prior to this time. We believe it is important that data used to determine Factor 3 are data that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes). It is our belief that hospitals expend more resources to ensure data accuracy when data are publicly available and used for payments. For example, the National Quality Forum (NQF) first endorsed quality measures for readmissions for heart failure (HF) in May 2008 and acute myocardial infarction (AMI) and pneumonia (PN) in October 2008. HF was subsequently adopted in the Hospital Inpatient Quality Reporting Program in the FY 2009 IPPS rule and AMI and PN in the CY2009 OPPS rule. All three were adopted for the FY 2010 HIQR program and publicly reported in Hospital Compare in 2009. More recently, starting in FY 2013, all three were used to determine a payment adjustment under 1886(q). As the measures became linked with payment, CMS has received an increasing number of questions regarding and requests to refine these measures, leading us to believe that hospitals are increasingly focused on ensuring that their data are correct. Furthermore, it is also our belief that auditing plays an important role in ensuring data accuracy by identifying and remediating problem areas and/or hospitals as well as by having a sentinel effect in others. For example, each year, CMS and its intermediaries work with hospitals to review salary and wage data reported on Worksheet S–3 of the Medicare cost report for use in determining the wage index. This extensive process identifies errors and ensures that anomalous data are reviewed, corrected as needed, and documented. Due to stakeholder concerns and our belief in the importance of using data that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes), for FY 2014, we have serious concerns about proposing using Worksheet S–10 to determine the amount of uncompensated care.

While the statute instructs the Secretary to estimate the amounts of uncompensated care for a period ''based on appropriate data,'' section 1886(r)(2)(C)(i) permits the Secretary to use alternative data ''in the case 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'' for the numerator of Factor 3. For the denominator of that quotient, section 1886(r)(2)(C)(ii) requires the Secretary to use ''the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection for such period (*as so estimated, based on such data*). (Emphasis added.) The phrase ''as so estimated, based on such data'' in the latter section can be reasonably interpreted to require the calculation to similarly be based on the same data as is used to estimate the numerator of the quotient in Factor 3, including any alternative data which is determined to be a better proxy for the costs of treating the uninsured. As a result of our concerns regarding variations in the data reported on the Worksheet S–10, we believe that it is appropriate to consider the use of alternative data, at least in FY 2014, the first year that this provision is effective, and possibly additional years until hospitals have adequate experience reporting all of the data elements on Worksheet S–10. We note that this is consistent with input we received from some stakeholders in response to the CMS National Provider Call in January 2013, who stated their belief that existing FY 2010 and FY 2011 data from the Worksheet S–10 cannot be used for implementation of 1886(r) and who requested the opportunity to re-submit the data once more specific instructions were issued by CMS. Accordingly, we examined alternative data sources that could be used to allow time for hospitals to gain experience with and to improve the accuracy of their S–10 reporting. For the reasons described above, we believe it would be appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) as alternative data for the first year or years of implementation.

In order to implement the statutory requirements for Factor 3 using alternative data, we must: (1) Determine whether alternative data would be a better proxy for the treatment costs of the uninsured than the information available on the Worksheet S–10; (2) identify a source for this alternative data; and (3) determine the timing and manner of computing the quotient for each hospital.

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 regarding the accuracy and consistency of the data reported on the Worksheet S–10, we believe that this alternative data, which is currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. Accordingly, we propose to use 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 describe our proposal and rationale more fully below and seek public comment.

As a preliminary matter, we note that precise data on health care costs are difficult to obtain. We note that for Medicare payment purposes, we estimate those costs using reported charges and cost-to-charge ratios. This approach to estimating costs is what is used on Worksheet S–10 to determine costs for charity care and bad debt. Even though we do not believe it is appropriate to look beyond the Medicare cost report for alternative data because all hospitals are required to report data on that cost report, we think that it is important to point out that data on uninsured patients is difficult to find in a comprehensive manner on a hospital-specific basis. In a September 2002 report, Analysis of the Joint Distribution of Disproportionate Share Hospital Payments, RAND and Urban Institute researchers describe this difficulty, citing as an example how detailed inpatient utilization data on self-pay patients were available only for the sample of hospitals (20 percent sample) from the 24 states included in AHRQ's HCUP database.[25]

While Worksheet S–10 does contain some information regarding the treatment costs of the uninsured, most notably of those uninsured patients who qualify for charity care at an individual hospital, for the reasons described above, we are concerned about the use of information reported on the Worksheet S–10 as appropriate data for FY 2014 and possibly additional years. As a result of these concerns, in identifying alternative data that could serve as a proxy for the treatment costs of the uninsured, we must consider methods other than costs to approximate the resources expended by hospitals to treat uninsured patients. One such method is utilization. A hospital's costs for treating uninsured patients are a function of its input costs and utilization of services. In accordance with the statute, in order to determine Factor 3, a hospital-level estimate of uncompensated care is required. Such an estimate can be constructed using detailed data regarding specific items or services. However, such data are not available to us. In contrast, hospital level data measuring utilization as inpatient days or discharges are available. While we note that inpatient days or discharges would be more precise if they took into account the relative resource utilization of individual patients, such as case mix, no such data are available to us. In the September 2002 report discussed above, RAND and Urban Institute researchers asserted that without specific case mix data for low income populations, inpatient days are preferable to discharges as a way to measure utilization. Therefore, we believe that utilization based upon inpatient days is an appropriate method to approximate costs for the treatment costs of the uninsured.

We further believe that utilization by insured low-income patients, such as Medicaid patients or Medicare patients that receive SSI benefits (Medicare SSI), can be a reasonable proxy for utilization by uninsured patients. In its 2000 report on American's Health Care Safety Net, the Institute of Medicine considers uninsured individuals, low-income underinsured individuals, Medicaid beneficiaries, and patients with special health care needs all as vulnerable populations.[26] We note that when studying access to care, researchers may study Medicaid and/or low-income populations (e.g., health outcomes, utilization, etc.) in order to understand more broadly the impact of similar policy interventions for other vulnerable populations.[27] For example, recently, researchers have studied the effects of Medicaid expansions to gauge the effects of these expansions on health status and other indicators to inform policymakers as these expansion efforts continue.[28] Researchers have also studied the ability of Medicaid patients to gain access to outpatient care in an effort to highlight the ramifications of various policy interventions, such as mandatory co-payments and utilization restrictions.[29] We believe that this type research is often used by state and other policy makers to evaluate how Medicaid and other public health insurance can expand access to care to uninsured populations.

While the report by RAND and the Urban Institute cited above found shortcomings in how well both Medicaid and Medicare DSH target funds towards safety net hospitals, another key finding of the report was that the allocation methods used by these programs target funds to safety net hospitals at least as well as the alternative allocation methods they examined. The allocation method used by Medicare for Medicare DSH is the sum of two computations. The first computation, defined at 42 CFR 412.106(b)(2), known as the SSI ratio or Medicare fraction, is the proportion of a hospital's Medicare SSI days relative to Medicare days. The second computation, defined at 42 CFR 412.106(b)(4), known as the Medicaid fraction, is the proportion of a hospital's Medicaid days relative to total days. The by RAND and the Urban Institute study also found that the choice of patient populations used to evaluate how well Medicare and Medicaid DSH funds are allocated is important. The study notes that including Medicare SSI beneficiaries along with all other low-income patients generally performed better, resulting in a better targeting of these payments towards safety net hospitals. Therefore, we believe the utilization of insured low income patients defined as insured low-income days, or inpatient days of Medicaid patients plus inpatient days of Medicare-SSI patients could be a proxy for the treatment costs of uninsured patients. Currently, for the Medicare DSH adjustment, hospitals report utilization for Medicaid and Medicare SSI patients in accordance with the regulations at 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively. Specifically, we would define inpatient days for Medicaid patients as they are defined in 42 CFR 412.106(b)(4) and inpatient days for Medicare-SSI patients as they are defined at § 412.106(b)(2)(i). A hospital's individual insured low-income insured days based on this calculation would represent that hospital's numerator for Factor 3. The sum of the low-income insured days under this calculation for all the hospitals that we estimate would receive DSH payments (and thus the uncompensated care payment) for FY 2014 would represent the denominator of Factor 3.

It is important to point out that when these insured low-income utilization data are used to determine Medicare DSH payments, they are subject to additional computations as described in 42 CFR 412.106(b) and 412.106(d).

[25] Wynn, B. et al. Analysis of the Joint Distribution of Disproportionate Share Hospital Payments. PM–1387–ASPE. September 20, 2002 *http://www.urban.org/UploadedPDF/410975_ASPEDSH_final.pdf.*

[26] Marion Ein Lewin and Stuart Altman, Editors; Committee on the Changing Market, Managed Care, and the Future Viability of Safety Net Providers, Institute of Medicine. America's Health Care Safety Net: Intact but Endangered. 2000. *http://www.nap.edu/catalog/9612.html.*

[27] John K. Iglehart. Medicaid. N Engl J Med 1993; 328:896–900. March 25, 1993.

[28] Benjamin D. Sommers, M.D., Ph.D., Katherine Baicker, Ph.D., and Arnold M. Epstein, M.D. Mortality and Access to Care among Adults after State Medicaid Expansions. N Engl J Med 2012; 367:1025–1034. September 13, 2012.

[29] The Medicaid Access Study Group. Access of Medicaid Recipients to Outpatient Care. N Engl J Med 1994; 330:1426–1430. May 19, 1994.

Therefore, using these data to determine Factor 3 will lead to a different set of results than using these data to determine hospitals' Medicare DSH payments.

We believe that the data in the Medicare cost report (and data that are used to update the SSI ratios in the cost report) are acceptable for use as a source for this alternative data because they include data for all Medicare hospitals. For the reasons described above, we considered data elements from the Medicare cost report that have been historically publicly available, subject to audit, and used for payment purposes, as alternative data for the costs of subsection (d) hospitals for treating the uninsured. Worksheet S–3, Part I of the CMS–2552–96 version of the Medicare cost report and Worksheet S–2, Part I of the CMS 2552–10 version of the Medicare cost report contain information on the utilization of Medicaid patients. Specifically, it contains information regarding Medicaid days (i.e., the numerator of the Medicaid fraction). The SSI ratios can be found in Worksheet E, Part A and hospitals' SSI ratios are reported by CMS on the Medicare DSH Web site, by Federal fiscal year, and include a hospital's Medicare SSI days. We point out that CMS calculates the SSI ratios using the MedPAR claims data and updates them annually in accordance with the process and timing set forth in the FY 2011 IPPS rule (75 FR 50282), generally issuing them in the Spring of each year for the federal fiscal year two years prior. For instance, we would expect that the SSI ratios for FY 2011 would be made available in the Spring of 2013. SSI ratios can be downloaded from *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. The SSI ratios for a Federal fiscal year are the data that would ultimately be used in Worksheet E, Part A to determine a hospital's Medicare DSH adjustment for that fiscal year. While a hospital may choose to have its DSH payments settled using an SSI ratio based on the hospital's cost reporting period, this choice will vary by hospital and the timing of this choice will vary. As a result, a hospital's decision whether to have its SSI ratio calculated on the basis of its cost reporting period may not be available at the time we determine Factor 3 for a specific federal fiscal year. Therefore, in an effort to balance consistency and administrative efficiency with precision, we believe it is appropriate to use the SSI ratios based on the federal fiscal year.

Except for the data on Worksheet S–10, the Medicare cost report does not currently include information that would allow calculation of the treatment costs of uninsured patients. For the reasons described previously, for FY 2014 and possibly additional years, we have concerns with using these data. Accordingly, we propose to use Worksheet S–3 Part I of the CMS–2552–96 version of the Medicare cost report and Worksheet S–2, Part I of the CMS 2552–10 version of the Medicare cost report and data that are used to update the SSI ratios on that Worksheet E, Part A as the source of the alternative data to determine Factor 3 for FY 2014. We may propose to use data from Worksheet S–10 to determine uncompensated care costs in the future, once hospitals are submitting accurate and consistent data through this reporting mechanism.

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, the statute defines the numerator of the quotient as ''the amount of uncompensated care for such hospital *for a period selected by the Secretary...''* The statute defines the denominator as ''the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection *for such period.''* (Emphasis added.) As we have discussed above, we are proposing 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 proposed process, we also are proposing to determine the time period from which to estimate the numerator and denominator of the Factor 3 quotient in a way that will 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 using most recently available historical data 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.

We are proposing to estimate 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 are proposing to use data from the most recently available cost report for the Medicaid days 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. We note that these data are publicly available, subject to audit, and used for payment purposes. While we recognize that older data also meet these criteria, we often use the most recently available data for payment determinations. Therefore, for FY 2014, we are proposing to use data from the 2010/2011 cost reports for the Medicaid days and the FY 2011 SSI ratios for the Medicare-SSI days (or, if the FY 2011 SSIs are unavailable, the FY 2010 SSI ratios) to estimate Factor 3 for FY 2014.

To summarize, for FY 2014, in response to stakeholder concerns regarding data variability and lack of reporting experience with Worksheet S–10, we propose to determine Factor 3 using insured low-income patient days from the 2010/2011 cost reports (including the FY2011 or FY 2010 SSI ratios, whichever represents the most recently available inputs prior to October 1, 2013) as alternative data which are a better proxy for the treatment costs of uninsured patients. We further propose to define insured low-income patient days 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.

We are proposing to add a new paragraph (g)(1)(iii) under § 412.106 of our regulations to define the methodology for calculating Factor 3.

We are inviting public comments on this proposal. Notwithstanding our concerns regarding Worksheet S–10, we are interested to hear commenters' views on the quality of the data reported on the Worksheet S–10, and whether it would be sufficient for use in determining uncompensated care amounts for fiscal year 2014, either by itself or in combination with other data. We also seek comment on how fast we could transition to the use of Worksheet S–10 data based upon increased reliability over time, including whether the data could be used to determine uncompensated care in FY 2014 either alone or in combination with other data.

In addition, we are proposing to estimate which hospitals would receive an empirically justified DSH payment in a given Federal fiscal year using the most recent data available. As we described previously, only hospitals that receive Medicare DSH payments in a fiscal year may receive an uncompensated care payment. However, because whether or not a hospital will actually receive Medicare DSH payment is not known until cost report

settlement and cost report settlement occurs several years after end of the federal fiscal year, we believe it is necessary to estimate which hospitals will receive Medicare DSH for a given fiscal year. Because the uncompensated care amounts for these hospitals are used to determine the denominator of Factor 3, this allows for the calculation of Factor 3 in advance of or during the federal fiscal year so that interim payments can begin during the fiscal year. We believe that this will create some level of predictability and finality for hospitals eligible for these payments, in addition to being administratively efficient.

Thus for FY 2014, the denominator for Factor 3 would reflect the estimated Medicaid and Medicare SSI patient days based on data from the 2010/2011 Medicare cost report (including the most recently available data that may be used to update the SSI ratios) for all hospitals that we estimate would receive an empirically justified DSH payment in FY 2014. The numerator of Factor 3 would be the estimated Medicaid and Medicare SSI patient days for the individual hospital based on its most recent 2010/2011 Medicare cost report data (including the most recently available data that may be used to update the SSI ratios). We propose to calculate a numerator for all subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a DSH payment regardless of whether we estimate that the hospital would receive DSH payments in the respective Federal fiscal year. In that way, if a hospital becomes eligible to receive the empirically justified DSH payment and also an uncompensated care payment, we will be able to finalize its uncompensated care payment efficiently and without affecting the uncompensated care payments of other hospitals.

We believe that this proposed approach strikes an appropriate balance between administrative efficiency, finality, and predictability in payments. Therefore, we also are proposing to publish a table or tables listing Factor 3 for all hospitals that we estimate would receive empirically justified DSH payments in a fiscal year (that is, hospitals that would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) and subsection (d) Puerto Rico hospitals that have the potential of receiving a DSH payment in the event that they receive an empirically justified DSH payment for the fiscal year as determined at cost report settlement. We are also proposing that hospitals have 60 days from the date of display of the 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 has closed or converted to a CAH. We will notify hospitals concerning the specifics of this process in program instructions after the final rule. For FY 2014, we will allow hospitals 60 days from the date of display of the 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, and we may allow an additional (perhaps shorter) such period after the publication of the final rule. For hospitals that were not estimated to receive an empirically justified DSH payment for a fiscal year, but ultimately qualify for such a payment at cost report settlement, we would make the full uncompensated care payment at that time. In the case of hospitals that we estimated would receive an empirically justified Medicare DSH payment for a fiscal year and that received interim empirically justified Medicare DSH payments and uncompensated care payments, but are found to be ineligible for DSH payments at cost report settlement, we would recover the overpayment. However, we are proposing only to calculate the denominator once, at the time of the IPPS/LTCH PPS final rule each year. We are not proposing to recalculate the denominator at the time when cost reports are settled and final eligibility determinations for uncompensated care (and empirically justified Medicare DSH) payments are made. We discuss our proposals for interim payments and reconciliation processes later in this preamble.

For the purpose of this proposed rule, we are posting proposed tables listing Factor 3 for the hospitals that we have estimated would receive Medicare DSH payments for FY 2014 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. We request that hospitals review these tables. In order to ensure that we have sufficient time to incorporate any updated information in the tables for the final rule, hospitals should notify CMS in writing within 60 days from the date of display of this proposed rule of any change in a hospital's subsection (d) hospital status. As we state above, for FY 2014, we may allow an additional (perhaps shorter) such period after the publication of the final rule.

Our estimates of eligibility to receive FY 2014 Medicare DSH payments are based on the December 2012 update of the Provider Specific File that lists the most recently available DSH patient percentage (DPP) and DSH payment adjustments for hospitals that qualify to receive DSH payments. We estimate that 2,349 hospitals, or 68 percent of all applicable hospitals, would be eligible for DSH payments in FY 2014. The proposed Factor 3 is based on the December 2012 update of the Medicare Hospital Cost Report and FY 2010 SSI ratios. The data from these 2,349 hospitals is used to determine the denominator for Factor 3. However, we will estimate a Factor 3 numerator for each subsection (d) and subsection (d) Puerto Rico hospital that has the potential of receiving DSH payments for FY 2014 and therefore of qualifying for the uncompensated care payment in FY 2014. We intend to update in the final rule the list of hospitals that we estimate will be eligible for DSH payments for FY 2014 and our estimate of Factor 3 using more recent data and verified hospital notifications regarding hospital status (for example, closures).

e. Limitations on Review

Section 1886(r)(3) of the Act provides that there will be no administrative or judicial review under section 1869 of the Act, 1878 of the Act, or otherwise for any of the following:

- Any estimate of the Secretary for purposes of determining the factors described in paragraph (2) of section 1886(r) of the Act.
- Any period selected by the Secretary for such purposes.

We are proposing to codify this policy in new § 412.106(g)(2) of our regulations.

We invite public comment on this proposal.

f. Proposed Operational Considerations

As discussed earlier in section V.F.3.d. of the preamble of this proposed rule, and in accordance with section 1886(r)(2) of the Act, only subsection (d) hospitals that receive empirically justified Medicare DSH payments in a given Federal fiscal year will also receive the uncompensated care payment (that is, Factor 1 times Factor 2 times Factor 3) for that given Federal fiscal year. In addition, as discussed above in this section, we are proposing that subsection (d) Puerto Rico hospitals that receive empirically justified Medicare DSH payments in a given Federal fiscal year would also receive the uncompensated care payment (that is, Factor 1 times Factor 2 times Factor 3) for that given Federal fiscal year. As we discussed above, we intend to estimate Factor 3 for each subsection (d) and subsection (d) Puerto Rico hospital with the potential to receive a DSH payment prior to the

beginning of the Federal fiscal year and intend to make that information available via our Web site. *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.

Specifically, we are proposing to make interim uncompensated care payments on the basis of our best available estimates concerning the eligibility of each hospital for empirically justified Medicare DSH payments and our best available calculations concerning the amount of the uncompensated care payments that the hospital is eligible to receive. We intend to make these interim uncompensated care payments on a periodic basis and not on a per discharge basis. As discussed above, we believe that this approach is more consistent with the plain language of the statute describing the additional payment, which includes no information from which it would be possible to infer that the payment should be made on a per discharge basis. We believe that this is the most administratively efficient means to distribute a set dollar amount to individual hospitals and also creates an appropriate level of predictability for hospitals. If we were to make these interim uncompensated care payments on a per discharge basis, unless a hospital's Medicare utilization is identical to the period used to determine the per discharge payment level, it is certain that Medicare would overpay or underpay. By making interim payments periodically, we can virtually eliminate the possibility that Medicare pays a higher or lower amount than intended and limit the need for reconciliation to whether a hospital is eligible for Medicare DSH and thus the entire uncompensated care payment at cost report settlement.

We also are proposing to make a final determination concerning eligibility for uncompensated care payments at the time of cost report settlement. As a result of this proposal, our operational system must be able to handle the various situations that may arise between interim and final eligibility determinations. For example, a hospital may receive empirically justified DSH payments and uncompensated care payments based on an initial determination that the hospital is eligible for such payments, but the hospital may then be determined to be ineligible for such payments at cost report settlement. In such situations, we must be prepared and able to recoup the interim empirically justified DSH payments and uncompensated care payments that the hospital received.

For each Federal fiscal year, as we proposed earlier in this section, we intend to estimate which hospitals will receive an empirically justified DSH payment (that is, eligible hospitals). We are proposing to provide periodic payments to these hospitals during the relevant Federal fiscal year so that they can receive their uncompensated care payments on an interim basis. For a fiscal year, each eligible hospital's interim uncompensated care payments will be determined by multiplying the final values for Factor 1, Factor 2, and Factor 3 for that year and dividing the amount by the number of periods over which the interim payments will be made.

Because we are using historical data to estimate each hospital's eligibility for empirically justified DSH payments in FY 2014 and subsequent years, a reconciliation process will be necessary to account for cases in which a hospital's eligibility for such payments changes after we have published our estimates during the rulemaking process. For example, a hospital that had not been estimated to be eligible for these payments may become eligible during the course of a given payment period. In such cases, our estimates would have indicated that the hospital was ineligible for empirically justified DSH payments and therefore ineligible for uncompensated care payments. That hospital would not receive interim payments. However, if the data available at cost report settlement were to indicate that the hospital is eligible for an empirically justified DSH payment, the hospital would become eligible for an uncompensated care payment based on that hospital's Factor 3 value.

Therefore, we are proposing that at cost report settlement, the fiscal intermediary/MAC will make a final determination concerning whether each hospital is eligible for empirically justified Medicare DSH payments and, therefore, uncompensated care payments in FY 2014 and each subsequent year. In the case where a hospital received interim payments for its empirically justified Medicare DSH payments and uncompensated care payments for FY 2014 or a subsequent year on the basis of estimates prior to the payment year, but is determined to be ineligible for the empirically justified Medicare DSH payment at cost report settlement, the hospital would no longer be eligible for either payment and CMS would recoup those monies. For a hospital that did not receive interim payments for its empirically justified DSH payments and uncompensated care payments for FY 2014 or a subsequent year, but at cost report settlement is determined to be eligible for DSH payments, the fiscal intermediary/MAC would calculate the uncompensated care payment for such a hospital based on the Factor 3 value determined prospectively for that fiscal year.

We are proposing to codify this policy regarding the manner and timing of payments in new § 412.106(h) of our regulations.

We invite public comment on this proposal.

The reconciliations at cost report settlement would be based on the values for Factor 1, Factor 2, and Factor 3 that we have finalized prospectively for a Federal fiscal year. For example, a hospital that was estimated by CMS to receive empirically justified DSH payments for FY 2014 and received interim uncompensated care payments would not receive a different uncompensated care payment amount if the fiscal intermediary/MAC determined that the hospital remained eligible for empirically justified DSH payments at cost report settlement. In other words, we are not proposing to include a reestimation of Factor 1, Factor 2, or Factor 3 in the reconciliation process we are describing. Rather, Factor 1, Factor 2, and Factor 3 are estimates determined prospectively using methodologies we establish through rulemaking. We recognize that, under this proposal, we may pay a total amount that could either be more or less than the product of Factor 1 and Factor 2. However, we believe this is inherent in the use of estimates to determine the Factors, similar to the manner in which we estimate the amount of total outlier payments under section 1886(d)(5)(A)(iv) although, as in this case, the amount of actual total outlier payments might vary from that estimate. We do not know of any reason to believe that there will be a bias toward systematic overpayment or underpayment from year to year.

We are proposing to codify this policy at § 412.106(g)(1)(iv) of our regulations.

We are inviting public comments on this proposal, especially in regard to whether we should include Factor 3 within the reconciliation process. Depending on the comments, we may revise our proposed policy in the final rule so that at the time of cost report settlement and reconciliation a hospital's final uncompensated care payments could be based on Factor 3 numerators and denominators estimated using more recent cost report data (and associated inputs). In addition, we may revise our proposed reconciliation process, as appropriate, to account for any policy changes that we make in the

final rule to the proposals in this proposed rule.

We also note that the uncompensated care payment will be reported on the Medicare Hospital Cost Report. We recognize that hospitals have their own cost reporting periods that may differ from the Federal fiscal year and that may span more than one Federal fiscal year. We are proposing that hospitals receive their uncompensated care payments with respect to the fiscal year in which their cost report begins. For example, if a hospital is estimated to be eligible for the empirically justified DSH payment and also an uncompensated care payment in FY 2014 and has a cost report period of January 1, 2014 through December 31, 2014, this hospital would begin to receive interim payments for its uncompensated care on October 1, 2013. If, at cost report settlement, this hospital remained eligible for an empirically justified DSH payment, then the hospital would receive its FY 2014 uncompensated care payment on its cost report for the cost reporting period beginning on January 1, 2014 (that is, the hospital would neither owe nor be owed monies for its uncompensated care payment). As another example, if that same hospital is no longer eligible for an empirically justified Medicare DSH payment at the time of settlement of its cost report for the cost reporting period beginning January 1, 2014, the hospital would be required to pay back the interim payments it received for its uncompensated care payments. We note that this methodology would not delay the full payment of FY 2014 payments to hospitals with cost reporting periods that begin after October 1, 2013. While it is possible to align interim and final payments for the uncompensated care payment with individual hospital's cost reporting periods, we believe it administratively efficient and practical to pay the uncompensated care payment on the basis of the Federal fiscal year because that is how it is determined, and to reconcile that amount in the cost reporting period that begins in the respective Federal fiscal year. If this proposal is finalized, we will revise the cost report accordingly. We are inviting public comments on our proposal.

g. National Provider Call

On January 8, 2013, CMS hosted a National Provider Call regarding the implementation of section 3133 of the Affordable Care Act. During this call, CMS asked Dobson DaVanzo and Associates, LLC. with its subcontractor, KNG Health Consulting, LLC, to present information regarding alternative definitions, measures, and data sources for the various estimates required by section 1886(r) of the Act, including the rate of uninsured individuals under the age of 65 years and hospital-specific uncompensated care. Approximately 1,304 participants participated in this call. The presentation materials from the call are available on the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2013-01-08-ACA* to submit public comments to CMS for consideration through January 15, 2013, when we undertook rulemaking and other activities related to implementation of section 1886(r) of the Act. Approximately 64 organizations submitted comments either on the National Provider Call or subsequent to the National Provider Call. We appreciate this input and have considered the issues raised by the commenters in developing the proposals discussed above. The report ''Improvements to Medicare Disproportionate Share (DSH) Payments'' discusses the issues raised in this National Provider Call. A summary of the comments on the National Provider Call has also been prepared. The report and summary can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.

F. Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Backgound

Section 1885(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.) As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), section 3124 of the Affordable Care Act extended the expiration of the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Public Law 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology by striking out ''October 1, 2011'' and inserting ''October 1, 2012''. Section 3124(b) of the Affordable Care Act made conforming amendments to sections 1886(b)(3)(D) and 1886(b)(3)(D)(iv) of the Act.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287 and 50414), we amended the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2012. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), we did not make any additional changes to the MDH regulatory text for FY 2012. As discussed below, the ATRA (Pub. L. 112–240) amended the Act to extend the MDH program through the end of FY 2013.

2. Provisions of the ATRA for FY 2013

a. Background

Prior to the enactment of the ATRA, under section 3124 of the Affordable Care Act, the MDH program authorized by section 1886(d)(5)(G) of the Act was set to expire at the end of FY 2012. Section 606 of the ATRA amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an additional 1-year extension of the MDH program, effective from October 1, 2012 to September 30, 2013 (FY 2013). Section 606 of the ATRA also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Prior to the enactment of the ATRA, in the FY 2013 IPPS/LTCH PPS final rule, we discussed the expiration of the MDH program at the end of FY 2012 (77 FR 53413 through 53414) and revised the SCH regulation at § 412.92(b) to change the effective date of SCH status for MDHs that apply for SCH status with the expiration of the MDH program (77 FR 53404 through 53405).

In a FY 2013 IPPS notice issued in the **Federal Register** on March 7, 2013 (78 FR 14689), we announced the extension of the MDH program for FY 2013 in accordance with the provisions of section 606 of the ATRA. In that notice, we explained that, as a result of section 606 of the ATRA, the MDH program is now extended for 1 additional year, through the end of FY 2013 (that is, effective October 1, 2012 through September 30, 2013). The FY 2013 IPPS notice explained how providers may be affected by the ATRA extension of the MDH program and described the steps to reapply for MDH status for FY 2013, as applicable. Generally, a provider that was classified as an MDH at the end of FY 2012 (that is, as of September 30, 2012) will be reinstated as an MDH effective October 1, 2012, with no need to reapply for MDH classification. However, if the MDH had classified as

a sole community hospital (SCH) or cancelled its rural classification under § 412.103(g) effective on or after October 1, 2012, the effective date of MDH status may not be retroactive to October 1, 2012. In the FY 2013 IPPS notice, we also stated that we intended to make conforming changes to the regulations at §§ 412.108(a)(1) and (c)(2)(iii) in future rulemaking to reflect the statutory changes made by section 606 of the ATRA. We refer readers to the FY 2013 IPPS notice (78 FR 14689 through 14694) for additional information on the extension of the MDH program through FY 2013 pursuant to section 606 of the ATRA and for additional information on how and when MDH status will be determined for hospitals classified as MDHs prior to the September 30, 2012 expiration of the program.

b. Proposed Conforming Regulatory Changes

In this proposed rule, we are proposing to make conforming changes to the regulations at §§ 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2013 made by section 606 of the ATRA.

c. Expiration of the MDH Program

Because section 606 of the ATRA extends the MDH program through FY 2013 only, effective FY 2014, the MDH program will no longer be in effect. Because the MDH program is not authorized by statute beyond FY 2013, beginning in FY 2014, all hospitals that previously qualified for MDH status will no longer have MDH status and will be paid based on the Federal rate.

As noted earlier, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our SCH policies to allow MDHs to apply for SCH status and be paid as such under certain conditions, following expiration of the MDH program at the end of FY 2012. We codified these changes in the regulations at § 412.92(b)(2)(i) and § 412.92(b)(2)(v). For additional information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53674). We note that those same conditions apply to MDHs that intend to apply for SCH status with the expiration of the MDH program at the end of FY 2013. Specifically, the existing regulations at § 412.92(b)(2)(i) and (b)(2)(v) allow for an effective date of approval of SCH status that is the day following the expiration date of the MDH program. In accordance with these regulations, in order for an MDH to receive SCH status effective October 1, 2013, it must apply for SCH status at least 30 days before the end of the MDH program; that is, the MDH must apply for SCH status by August 31, 2013. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program provision; that is, the MDH must request that the SCH status, if approved, be effective October 1, 2013, immediately after its MDH status expires with the expiration of the MDH program at the end of FY 2013, on September 30, 2013.

We note that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the October 1, 2013 effective date upon approval if it does not apply by the August 31, 2013 deadline. The provider would instead be subject to the usual effective date for SCH classification, that is, 30 days after the date of CMS' written notification of approval as specified at § 412.92(b)(2)(i).

G. Hospital Readmissions Reduction Program: Proposed Changes (§§ 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 subsection (q) to section 1886 of 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. Pursuant to 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 subsection (d) (determined without regard to subsection (o) [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 subsection (d).'' Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection(d) 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 subsection (d)'' for certain hospitals. Specifically, section 1886(q)(2)(B) of the Act states that ''[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital . . . the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).'' 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''.

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 describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of 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 Readmission Ratio . . . for such hospital for such applicable period minus 1.'' The ''excess readmission ratio is a hospital-specific ratio based on each applicable condition. Specifically, section

1886(q)(4)(C) of the Act defines the excess readmission 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.

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) . . . 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 3 conditions for which measures have been endorsed . . . to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission 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, the ''applicable period'' is the period from which data are collected in order to calculate various ratios and 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 for ''specified hospitals'' in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Overview

We have been implementing the requirements of the Hospital Readmissions Reduction Program in rulemakings, and will continue to do so. 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, we addressed the issues of the selection of readmission measures and the calculation of the excess readmission ratio, which will be used, in part, to calculate the readmission adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the portions of section 1886(q) of the Act related to the following provisions:

- Selection of applicable conditions;
- Definition of ''readmission'';
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the excess readmission ratio; and
- Definition of ''applicable period'';

With respect to the topics of ''measures for readmission'' for the applicable conditions, and ''methodology for calculating the excess readmission ratio,'' we specifically addressed the following:

- Index hospitalizations;
- Risk adjustment;
- Risk standardized readmission rate;
- Data sources; and
- Exclusion of certain readmissions.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized our policies that relate to the calculation of the hospital readmission payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in the final rule, we addressed the portions of section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs and hospitals paid under section 1814(b) of the Act;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions and aggregate payments for all discharges;
- Applicable hospital;
- Limitations on review;
- Reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections.

In the FY 2013 IPPS/LTCH PPS final rule, we 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.

3. FY 2014 Proposals for the Hospital Readmissions Reduction Program

a. Overview

In this proposed rule, for FY 2014 and beyond, we are proposing to—

- Refine the readmissions measures and related methodology for the current applicable conditions (section V.G.3.b. of this preamble);
- Expand the ''applicable conditions'' for FY 2015 (section V.G.3.c. of this preamble);
- Specify additional policies for hospitals paid under section 1814(b)(3) of the Act (§ 412.154(d)), including the process to be exempted from the Hospital Readmissions Reduction Program and the definition of ''base operating DRG payment amount'' (section V.G.3.d. of this preamble);
- Specify the proposed adjustment factor floor for FY 2014 (section V.G.3.e. of this preamble);
- Specify the proposed applicable period for FY 2014 (section V.G.3.f. of this preamble);
- Refine the methodology to calculate the aggregate payments for excess readmissions (section V.G.3.g. of this preamble); and
- Clarify the process for reporting hospital-specific information, including the opportunity to review and submit corrections (section V.G.3.h. of this preamble).

b. Proposed Refinement of the Readmission Measures and Related Methodology for FY 2014 and Subsequent Years Payment Determinations

(1) Overview of the Inclusion of Planned Readmissions for the Calculation of the FY 2014 Readmissions Adjustment Factors

In the FY 2012 IPPS/LTCH PPS final rule, we adopted acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN) readmission measures for the Hospital Readmissions Reduction Program payment determinations beginning with FY 2013. During development of the three readmission measures for AMI, HF, and PN, we consulted with medical experts to identify readmissions that are typically scheduled as followup care for each specific condition within 30 days of discharge. We categorized these readmissions as planned followup care and excluded them from being counted

as a readmission. The AMI measure finalized for the Hospital Readmissions Reduction Program included two revascularization procedures (coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI) (76 FR 51667)). We considered these procedures planned readmissions and excluded them from the readmission calculation as long as the readmissions were not for one of five acute conditions (HF, AMI, other acute/subacute forms of ischemic heart disease, arrhythmia, and cardiac arrest).

During development of the HF and PN readmission measures, we did not identify any readmissions that were typically planned as followup care at the time of the patient's discharge. Therefore, the readmission measures finalized for the Hospital Readmissions Reduction Program for these two conditions did not exclude any planned readmissions from the readmission calculation.

(2) Proposed Refinement of the Readmission Measures and Related Methodology for the FY 2014 and Subsequent Years Payment Determinations

Since the development and implementation of the initial three readmission measures adopted under the Hospital Readmissions Reduction Program, we have received comments from the medical community, other stakeholders, and the general public encouraging us to identify and not count as readmissions a broader range of planned readmissions. Stakeholders also made recommendations for expanding the number and types of planned readmissions during the public comment period for FY 2013 IPPS/LTCH PPS proposed rule (as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53382 through 53398)).

Stakeholders commented that readmission measures are intended to capture unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. In addition, stakeholders commented that planned readmissions do not generally signal poor quality of care. In response to stakeholders' concerns, we have worked with experts in the medical community, other stakeholders, and the public to broadly identify planned readmissions for procedures and treatments for exclusion from the readmission measures. Specifically, we developed an expanded ''planned readmission algorithm'' in the CMS Planned Readmission Algorithm Version 2.1 Report to identify planned readmissions across our readmission measures, and are proposing to apply the algorithm to the AMI, HF, and PN measures for FY 2014. The CMS Planned Readmission Algorithm Version 2.1 Report is available on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital_QualityInits/Measure-Methodology.html*.

We developed the algorithm based on a hospital-wide (not condition-specific) cohort of patients. We began the development by using the Agency for Healthcare Research and Quality's (AHRQ's) Clinical Classification Software (CCS) codes to group thousands of individual procedures and diagnoses codes into clinically coherent, mutually exclusive procedure and diagnosis categories (PROC–CCS categories and Diagnosis-CCS categories, respectively). A panel of independent, non-CMS clinicians then reviewed the procedure categories and identified those that are commonly planned and require admission. Clinicians also reviewed the diagnosis categories and identified those that were acute diagnoses likely requiring hospitalization. Using these procedure and diagnosis categories and some individual ICD–9–CM procedure and diagnoses codes in the categories, we developed an initial algorithm for identifying planned readmissions for a hospital-wide cohort of patients.

The algorithm underwent several reviews by stakeholders. We initially posted the detailed algorithm for informal public comment during the measurement development process in August 2011. The National Quality Forum (NQF) reviewed and made the algorithm available for public comment during its endorsement review of the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789). We also recruited 27 surgical subspecialists nominated by their specialty societies to review the algorithm and suggest refinements, which resulted in Version 2.1 of the Planned Readmission Algorithm. We are proposing to use this algorithm in the readmission measures under the Hospital Readmissions Reduction Program beginning with FY 2014. A detailed description of this algorithm is included later in this section.

As required by section 1886(q)(5)(A)(ii) of the Act, the first three applicable conditions of AMI, HF and PN, must use readmission measures that have been endorsed by the entity with a contract under section 1890(a) of the Act; and such endorsed measures must have exclusions for readmissions that are unrelated to the prior discharge (such as planned readmission or transfer to another applicable hospital). Because the statute requires that the readmission measures for the three current applicable conditions (AMI, HF and PN) be NQF-endorsed, we sought NQF's endorsement of the measures that were revised to include the CMS Planned Readmission Algorithm Version 2.1. NQF reviewed these revised measures through its ad hoc review process, which reviews previously endorsed measures that undergo material changes. Following ad hoc review, NQF endorsed the revised AMI (NQF #0505) and HF (NQF #0330) measures in January 2013 and the PN measure (NQF #0506) in (March 2013)).

(a) Description of CMS Planned Readmission Algorithm Version 2.1

This algorithm is a set of criteria for classifying readmissions as ''planned'' using Medicare claims. The algorithm identifies typical planned admissions that may occur within 30 days of discharge from the hospital.

We based the CMS Planned Readmission Algorithm on three principles:

- A few specific, limited types of care are always considered planned (obstetrical delivery, transplant surgery, maintenance chemotherapy, rehabilitation);
- Otherwise, a planned readmission is defined as a nonacute readmission for a scheduled procedure; and
- Admissions for acute illness or for complications of care are never planned.

The Planned Readmission Algorithm uses a flow chart and four tables of procedures and conditions to implement these principles and to classify readmissions as planned or unplanned. The flow chart and tables are available in a report, CMS Planned Readmission Algorithm Version 2.1, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital_QualityInits/Measure-Methodology.html*.

We incorporated the algorithm into each condition-specific and procedure-specific readmission measure. For most readmission measures, including the AMI, HF, and PN measures, we used one standard version of the algorithm—the CMS Planned Readmission Algorithm Version 2.1. However, for a subset of readmission measures, we revised the list of potentially planned procedures or acute primary diagnosis after applying the standard algorithm version because it was clinically indicated. For example, for the Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) readmission measure that we are proposing for FY 2015, we removed diagnostic cardiac

catheterization from the potentially planned procedure list because patients in the hip/knee measure are typically well enough to undergo elective surgery and would not be expected to need a catheterization within 30 days of discharge. The details of these adaptations are available in the CMS Planned Readmission Algorithm Version 2.1 report (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital_QualityInits/Measure-Methodology.html*).

(b) Proposed Counting of Readmissions that Occur After a Planned Readmission

In this proposed rule, we are proposing a related change to the AMI, HF, and PN measures to address unplanned readmissions that occur after a planned readmission but within 30 days of the patient's initial index discharge. The AMI measure finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666) counted unplanned readmissions for the index admission if they occurred within 30 days of discharge from the index admission, even if they occurred following planned readmissions (because the two other measures did not have any planned readmissions, this method of counting only applied to the AMI measure).

For the proposed revised AMI, HF, and PN measures, all of which now account for planned readmissions by incorporating the CMS Planned Readmission Algorithm Version 2.1, we are proposing the following additional change: If the first readmission is planned, it will not count as a readmission, nor will any subsequent unplanned readmission within 30 days of the index readmission. In other words, unplanned readmissions that occur after a planned readmission and fall within the 30-day post discharge timeframe would no longer be counted as outcomes for the index admission. The rationale for this proposed change is that, in this case, either the index or the planned readmission could have contributed to the patient's unplanned readmission. Therefore, it is unclear whether the unplanned readmission should be attributed back to the index admission. This proposed change in counting practice would affect a very small percentage of readmissions (approximately 0.3 percent of index admissions nationally for AMI, 0.2 percent for HF, and less than 0.1 percent for PN).). However, we intend to monitor trends in the proportion of planned readmissions for evidence of misuse or misapplication, and other unintended consequences.

(c) Anticipated Effect of the Proposed Changes of CMS Planned Readmission Algorithm Version 2.1 and Counting of Readmissions on the Readmission Measures

The proposed changes to the measures in this proposed rule would have had the following effects on the measures based on our analyses of discharges between July 2008 and June 2011, if these changes had been applied for FY 2013. We note that these statistics are for illustrative purposes only, and we are not proposing to revise the measure calculations for the FY 2013 payment determination. Rather, we are proposing to apply these changes to the readmissions measures for the FY 2014 payment determination and subsequent years.

Among hospitals that were subject to the Hospital Readmissions Reduction Program in FY 2013 (Table V.G.1), the number of eligible discharges based on the July 2008 through June 2011 data were 501,765 discharges for AMI; 1,195,967 discharges for HF; and 957,854 discharges for PN):

- The proposed 30-day readmission rate (excluding the planned readmissions) would decrease by 1 percentage point for AMI; 1.5 percentage points for HF; and 0.7 percentage point for PN.
- The new national measure (unplanned) rate for each condition would have been 18.2 percent for AMI; 23.1 percent for HF; and 17.8 percent for PN.
- The number of readmissions considered planned (and, therefore, not counted as a readmission) would increase by 4,942 for AMI; 17,512 for HF; and 7,084 for PN.

TABLE V.G.1—COMPARISON OF ORIGINAL AMI/HF/PN MEASURES FINALIZED IN FY 2013 RELATIVE TO PROPOSED REVISED AMI/HF/PN MEASURES FOR FY 2014

[Based on July 2008 through June 2011 discharges from 3,025 hospitals]

	AMI		PN		HF	
	Proposed revised measure	Original measure	Proposed revised measure	Original measure	Proposed revised measure	Original measure
Number of Admissions	501,765	501,765	957,854	957,854	1,195,967	1,195,967
Number of Unplanned Readmissions	91,360	96,302	170,396	177,480	276,748	294,260
Readmission Rate	18.2%	19.2%	17.8%	18.5%	23.1%	24.6%
Number of Planned Readmissions	12,811	7,869	7,084	0	17,512	0
Planned Readmission Rate	2.6%	1.6%	0.7%	0.0%	1.5%	0.0%
Percent of Readmissions that are Planned	12.3%	7.6%	4.0%	0.0%	6.0%	0.0%

In summary, we are proposing to use the proposed revised versions of the AMI, HF, and PN measures to calculate the payment adjustments for the Hospital Readmissions Reduction Program in FY 2014. We believe that the proposed revised measures will address stakeholder suggestions to broaden the number of planned readmissions and will result in a more accurate readmission calculation for purposes of the payment adjustment. We are proposing to update the measures to: (1) Incorporate the CMS Planned Readmission Algorithm Version 2.1 to identify planned readmissions; and (2) not count unplanned readmissions that follow planned readmissions. We are inviting public comments on this proposal.

c. Proposed Expansion of the Applicable Conditions for FY 2015

(1) Background

Under section 1886(q)(5)(B) of the Act, beginning with FY 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the three conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) . . . to the additional 4 conditions that have been identified by the Medicare

Payment Commission in its report to Congress in June 2007, and to other conditions and procedures as determined appropriate by the Secretary.'' The four conditions and procedures recommended by MedPAC are: (1) Coronary artery bypass graft (CABG) surgery; (2) chronic obstructive pulmonary disease (COPD); (3) percutaneous coronary intervention (PCI); and (4) other vascular conditions. Section 1886(q)(5)(A)(i) of the Act directs the Secretary, in selecting an ''applicable condition,'' to choose from among conditions and procedures ''that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary).''

In accordance with section 1886(q)(5)(A) of the Act, effective for the calculation of the readmissions payment adjustment factors in FY 2015, we are proposing to expand the applicable conditions and procedures to include: (1) Patients admitted for an acute exacerbation of COPD; and (2) patients admitted for elective total hip arthroplasty (THA) and total knee arthroplasty (TKA). At this point, it is not feasible for CMS to add readmission measures for three of the conditions identified by MedPAC in its 2007 Report to Congress (CABG, PCI, and other vascular conditions). We note that inpatient admissions for PCI and other vascular conditions seem to be decreasing, and these procedures are being performed more in hospital outpatient departments. This shift in setting for these procedures may make their future inclusion in the Hospital Readmssion Reduction Program more difficult and impracticable.

We are also exploring how we may address CABG in this program at a future time.

We are proposing inclusion of patients admitted for an acute exacerbation of COPD based on MedPAC's recommendations and may consider other recommendations in future rulemaking. While MedPAC did not recommend inclusion of patients admitted for elective THA and TKA, we consider this category appropriate for the Hospital Readmissions Reduction Program because it is a high-volume and high-expenditure procedure.

For example, in 2003, 202,500 primary hip arthroplasties and 402,100 primary total knee arthroplasties were performed.[30] The number of procedures performed has increased steadily over the past decade.[31] Although these procedures can dramatically improve patient health-related quality-of-life, they are costly. In 2005, annual hospital charges totaled $3.95 billion and $7.42 billion for primary THA and TKA, respectively.[32] The aggregate costs for THA are projected to increase by 340 percent over a 10-year period, to $17.4 billion per fiscal year by FY 2015, and for TKA, by 450 percent to $40.8 billion per fiscal year by 2015.[33] Medicare is the single largest payer for these procedures, covering approximately two-thirds of all THAs and TKAs performed in the United States.[34] THA and TKA procedures combined account for the largest procedural cost in the Medicare budget.[35] Therefore, as explained in detail below, we believe that it is appropriate to include THA/TKA as an applicable condition.

We developed a hospital-level, 30-day, all-cause, risk-standardized readmission measure for THA/TKA. NQF endorsed the measure (NQF #1551) in January of 2012. The measure incorporated the Planned Readmission Version 2.1 algorithm and excludes transfers. Accordingly, we believe that the THA/TKA measure met the criteria of applicable condition and are proposing it for the Hospital Readmissions Reduction Program.

The rationale for expanding the applicable conditions and the measures used to estimate the Excess Readmission Ratios are described in detail below.

(2) Proposed COPD Readmission Measure

COPD is a leading cause of readmissions to hospitals.[36] In 2007, the MedPAC published a report to Congress in which it identified the seven conditions associated with the most costly potentially preventable readmissions. Among these seven conditions, COPD ranked fourth.[37] Evidence also shows variation in readmissions for patients with COPD, supporting the finding that opportunities exist for improving care. The median, 30-day, risk-standardized readmission rate among Medicare fee-for-service patients aged 65 or older hospitalized for COPD in 2008 was 22.0 percent, and ranged from 18.33 percent to 25.03 percent across 4,546 hospitals.[38] Clinical trials and observational studies suggest that several aspects of care provided to patients hospitalized for exacerbations of COPD can have significant effects on readmission.[39 40 41 42] In addition, inclusion of this measure in the Hospital Readmissions Reduction Program aligns with CMS' priority objectives to promote successful transitions of care for patients from the acute care setting to the outpatient setting, and reduces short-term readmission rates. Therefore, we believe the COPD measure warrants inclusion in the Hospital Readmissions Reduction Program for FY 2015. We are inviting public comments on this proposal.

(3) Overview of COPD Measure: Hospital-Level, 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891)

The COPD readmission measure assesses hospitals' 30-day, all-cause risk-standardized rate of readmission for an acute exacerbation of COPD (AECOPD). In general, the measure uses the same approach to risk-adjustment and hierarchical logistic modeling (HLM) methodology that is specified for CMS' AMI, HF, and PN readmission measures previously adopted for this

[30] Kurtz S, Ong K, Lau E, Mowat F, Halpern M.: Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780–785.

[31] Ong KL, Mowat FS, Chan N, Lau E, Halpern MT, Kurtz SM. Economic burden of revision hip and knee arthroplasty in Medicare enrollees. Clin Orthop Relat Res. May 2006;446:22–28.

[32] Kurtz SM, Ong KL, Schmier J, et al.: Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am. Oct 2007;89 Suppl 3:144–151.

[33] Ibid.

[34] Ong KL, Mowat FS, Chan N, Lau E, Halpern MT, Kurtz SM. Economic burden of revision hip and knee arthroplasty in Medicare enrollees. Clin Orthop Relat Res. May 2006;446:22–28.

[35] Bozic KJ, Rubash HE, Sculco TP, Berry DJ. An analysis of medicare payment policy for total joint arthroplasty. Journal of Arthroplasty. 2008;23(6 Suppl 1):133–138.

[36] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. April 2 2009;360(14):1478–1428.

[37] Committee MPA. Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.

[38] Grosso L.M., Lindenauer P., Wang C., et al.: Hospital-level 30-day Readmission Following Admission for an Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Report prepared for the Centers for Medicare & Medicaid Services. 2011; Available at: *http://www.qualitynet.org/*.

[39] Global Strategy for Diagnosis M, and Prevention of COPD. 2009; Available at: *http://www.goldcopd.org/*.

[40] National Institute for Health and Clinical Excellence. Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care (Partial Update):. National Collaborating Centre for Acute and Chronic Conditions. Available at: *http://www.nice.org.uk/nicemedia/live/13029/49397/49397.pdf*.

[41] Walters JA, PG Gibson, R Wood-Baker, M Hannay, EH Walters. Systemic corticosteroids for acute exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009;CD001288(1).

[42] Lightowler JV, Wedzicha JA, Elliott MW, Ram FS. Non-invasive positive pressure ventilation to treat respiratory Failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. Bmj. 2003;326(7382).

program. Information on how the measure employs HLM can be found in the 2011 COPD Readmission Measure Methodology Report (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. This approach appropriately 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. The HLM methodology is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and, therefore, the patients' outcomes are not statistically independent) and sample sizes vary across hospitals. The measure methodology defines hospital case-mix based on the clinical diagnoses provided in the hospitals' claims for the hospitals' patient inpatient and outpatient visits for the 12 months prior to the hospitalization for COPD, as well as those present in the claims for care at admission. However, the methodology specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

We are providing a summary of the measure methodology below. For further details on the risk-adjustment statistical model, we refer readers to the 2011 COPD Readmission Measure Methodology Report that we have posted on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. NQF endorsed the measure (NQF #1891) in March 2013 (*http://www.qualityforum.org/QPS/1891*).

- Data Sources. The proposed COPD measure is claims-based. It uses Medicare administrative data from hospitalizations for fee-for-service Medicare beneficiaries hospitalized with an acute exacerbation of COPD (AECOPD).
- Outcome. The outcome for the COPD measure is 30-day, all-cause readmission, defined as an unplanned subsequent inpatient admission to any applicable acute care facility from any cause within 30 days of the date of discharge from the index hospitalization. A number of studies demonstrate that improvements in care at the time of discharge can reduce 30-day readmission rates.[43] [44] It is a timeframe that a readmission may reasonably be attributed to the hospital care and transitional period to a nonacute care setting.

The COPD readmissions measure assesses all-cause unplanned readmissions (excluding planned readmissions) rather than readmissions for acute exacerbations of COPD only. We are proposing this measure for several reasons. First, from the patient perspective, a readmission for any reason is likely to be an undesirable outcome of care, even though not all readmissions are preventable. Second, limiting the measure to COPD-related readmissions may limit the effort focus too narrowly rather than encouraging broader initiatives aimed at improving the overall care within the hospital and transitions from the hospital setting. Moreover, it is often hard to exclude quality issues and accountability based on the documented cause of readmission. For example, a patient with COPD who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to consider such a readmission to be unrelated to the care the patient received for COPD. Finally, while the measure does not presume that each readmission is preventable, interventions generally have shown reductions in all types of readmissions.

The measure does not count planned readmissions as readmissions. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 2.1 that detects planned readmissions that may occur within 30 days of discharge from the hospital. This algorithm is described briefly in section V.G.3.b.(2)(a) of the preamble of this proposed rule and more detailed information can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. For the COPD measures, unplanned readmissions that fall within the 30-day post discharge timeframe from the index admission would not be counted as readmissions for the index admission if they were preceded by a planned readmission (we refer readers to section V.G.3.b.(2)(b) of the preamble of this proposed rule on the proposed counting of readmissions that occur after a planned readmission).

- Cohort of Patients. COPD is a group of lung diseases characterized by airway obstruction. Patients hospitalized for an acute exacerbation of COPD (AECOPD) present with varying degrees of severity ranging from a worsening of baseline symptoms (dyspnea, cough, and/or sputum) to respiratory failure. To capture the full spectrum of severity of patients hospitalized for an AECOPD, the measure includes patients with a principal diagnosis of COPD, as well as those with a principal diagnosis of respiratory failure with a secondary diagnosis of an AECOPD. Requiring AECOPD as a secondary diagnosis helps to identify respiratory failure due to COPD exacerbation versus another condition (for example, heart failure). For detailed information on the cohort definition, we refer readers to the 2013 COPD Readmission Measure Updates and Specifications Report on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.
- Inclusion and Exclusion Criteria. The COPD measure includes hospitalizations for patients who are 65 years of age or older at the time of index admission and for whom there was a complete 12 months of Medicare fee-for-service (FFS) enrollment to allow for adequate risk-adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission); (2) admissions for patients having a principal diagnosis of COPD during the index hospitalization and subsequently transferred to another acute care facility (these are excluded because the measure focuses on discharges to a nonacute care setting such as the home or a SNF); (3) admissions for patients that are discharged against medical advice (AMA) (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge); (4) admissions for patients without at least a 30-day post-discharge enrollment in Medicare FFS (excluded because the 30-day readmission outcome cannot be assessed in this group); and (5) additional COPD admissions for patients within 30 days of discharge from an index COPD admission will be considered readmissions and not additional index admissions.
- Risk-Adjustment. The COPD measure adjusts for differences across hospitals in how at risk their patients

[43] Gulshan Sharma, Kou Yong-Fang, Freeman Jean L, Zhang Dong D, Goodwin James S.: Outpatient Follow-up Visit and 30-Day Emergency Department Visit and Readmission in Patients Hospitalized for Chronic Obstructive Pulmonary Disease. Arch Intern Med. Oct. 2010;170:1664–1670.

[44] Nelson EA, Maruish ME, Axler JL.: Effects of Discharge Planning and Compliance with Outpatient Appointments on Readmission Rates. Psychiatr Serv. July 1 2000;51(7):885–889.

are for readmission relative to patients cared for by other hospitals. The measure uses claims data to identify patient clinical conditions and comorbidites to adjust patient risk for readmission across hospitals, but does not adjust for potential complications of care. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race because risk-adjusting for these characteristics would hold hospitals with a large proportion of patients of minority race or low socioeconomic status to a different standard of care than other hospitals. Rather, this measure seeks to illuminate quality differences, and risk-adjustment for socioeconomic status or race would obscure such quality differences.

• Calculating the Excess Readmission Ratio. The COPD readmission measure uses the same methodology and statistical modeling approach as the AMI, HF, and PN measures. We published a detailed description of how the readmission measures estimate the Excess Readmission Ratio used in the Hospital Readmissions Reduction Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

(4) Proposed Adoption of the COPD Measure for the Hospital Readmissions Reduction Program

We are proposing to adopt the COPD measure in the Hospital Readmissions Reduction Program beginning in FY 2015. We also are proposing the COPD measure for use in the Hospital IQR Program for FY 2014 (discussed in section IX.A. of this preamble). We note that the set of hospitals for which this measure is calculated for the Hospital Readmissions Reduction Program differs from those used in calculations for the Hospital IQR Program. The Hospital Readmissions Reduction Program includes only subsection (d) hospitals as defined in 1886(d)(1)(B) of the Act and hospitals paid under section 1814(b)(3) of the Act (that is, Maryland hospitals), 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 believe that the COPD measure is appropriate for use in both programs. We are inviting public comments on this proposal.

(5) Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) Measure

THA and TKA are commonly performed procedures that improve quality of life. Between 2008 and 2010, over 1.4 million THA and TKA procedures were performed on Medicare FFS patients aged 65 years and older.[45] However, the costs of these procedures, especially to Medicare, are very high. Combined, THA and TKA procedures account for the largest procedural cost in the Medicare budget.[46] Evidence also shows variation in readmissions of patients with THA/TKA procedures, supporting the finding that opportunities exist for improving care. The median 30-day risk-standardized readmission rate among Medicare FFS patients aged 65 or older undergoing THA/TKA procedures between 2008 and 2010 was 5.7 percent, and ranged from 3.2 percent to 9.9 percent across 3,497 hospitals.[47] In addition, inclusion of a THA/TKA measure in the Hospital Readmissions Reduction Program aligns with CMS' priority objectives to promote successful transitions of care for patients from the acute care inpatient setting to the outpatient setting, and reduces short-term readmission rates. Therefore, we believe the THA/TKA measure warrants inclusion in the Hospital Readmissions Reduction Program for FY 2015.

(6) Overview of the THA/TKA Measure: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1551)

To better assess hospital care and care transitions for patients with elective THA/TKA procedures, we developed a hospital-level readmission measure for patients undergoing elective primary THA and/or TKA procedures. We finalized this measure for use in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We are proposing to include this measure, updated with the CMS Planned Readmission Algorithm Version 2.1 adapted for THA/TKA (discussed in section V.G.3.b.(2) of this preamble) to: (1) expand the applicable conditions for the Hospital Readmissions Reduction Program; (2) derive the Excess Readmission Ratio for patients with THA/TKA procedures; and (3) calculate the readmission payment adjustments in FY 2015. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521) for details of the measure specifications as well as the 2013 Hip/Knee Readmission Measures Updates and Specifications Report which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. NQF endorsed the measure in January 2012 (*http://www/qualityforum.org/QPS/1551*).

(7) Calculating the Excess Readmission Ratio

The THA/TKA readmission measure uses the same methodology and statistical modeling approach as the AMI, HF, and PN measures. We published a detailed description of how the readmission measures estimate the Excess Readmission Rate used in the Hospital Readmissions Reduction Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

(8) THA/TKA Measure for the Hospital Readmissions Reduction Program

We are proposing to adopt the THA/TKA measure in the Hospital Readmissions Reduction Program beginning in FY 2015. We also finalized this measure for use in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We note that the set of hospitals for which this measure is calculated for the Hospital Readmissions Reduction Program differs from the set of hospitals used in calculations for the Hospital IQR Program. The Hospital Readmissions Reduction Program includes only subsection (d) hospitals as defined in 1886(d)(1)(B) of the Act and hospitals paid under section 1814(b)(3) of the Act (that is, Maryland hospitals), while the Hospital IQR Program calculations include non-IPPS hospitals such as CAHs, cancer hospitals, and hospitals in the Territories. However, we believe that the THA/TKA measure is appropriate for use in both programs. We are inviting public comments on this proposal.

[45] Gross, L.M., Curtis, J.P., Lin, Z., et al.: Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA): Report prepared for the Centers for Medicare & Medicaid Services, 2012. Available on the Web site at: *http://www.qualitynet.org/*.

[46] Bozic KJ, Rubash HE, Sculco TP.: Berry DJ. An analysis of medicare payment policy for total joint arthroplasty. *J Arthroplasty*. Sep 2008;23(6 Suppl 1):133–138.

[47] Grosso L.M., Curtis J.P., Lin Z., et al.: Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA): Report prepared for the Centers for Medicare & Medicaid Services, 2012. Available on the Web site at: *http://www.qualitynet.org/*.

d. Proposals for Hospitals Paid Under Section 1814(b)(3) of the Act, Including the Process To Be Exempt From the Hospital Readmissions Reduction Program and Definition of ''Base Operating DRG Payment Amount'' for Such Hospitals (§ 412.152 and § 412.154(d))

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53397), the definition of ''applicable hospital'' under section 1886(q)(5)(C) of the Act also includes hospitals paid under section 1814(b)(3) of the Act (that is, acute care Maryland hospitals that would have otherwise been paid under the IPPS, but for the waiver under section 1814(b)(3) of the Act). Section 1886(q)(2)(B)(ii) of the Act allows the Secretary to exempt such hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings established by Congress for the program as applied to ''subsection (d) hospitals.'' Accordingly, a program established by the State of Maryland that could serve to exempt the State from the Hospital Readmissions Reduction Program would focus on those ''applicable'' Maryland hospitals operating under the waiver provided by section 1814(b)(3) of the Act; that is, those hospitals that would otherwise have been paid by Medicare under the IPPS absent this provision.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53384), we established criteria for evaluation of an annual report to CMS to determine whether Maryland should be exempted from the program each year. We codified this requirement at § 412.154(d) of the regulations. In addition, we specified that we will evaluate a report submitted by the State of Maryland documenting how its program meets those criteria. However, because the Hospital Readmissions Reduction Program was in its first year and Maryland's program was completing its first year, we specified that the evaluation of Maryland's program for measurable health outcomes and cost savings would not begin until FY 2014. In that same final rule, we explained that it would be premature to evaluate Maryland's readmission program on health outcomes and cost savings at that time, as we did not have sufficient information on which to evaluate Maryland's program because FY 2013 was first year of the Hospital Readmissions Reduction Program.

We noted that our finalized criteria to evaluate Maryland's program is for FY 2013, the first year of the program, and our evaluation criteria may change through notice-and-comment rulemaking as the Hospital Readmissions Reduction Program evolves.

In this proposed rule, we are proposing to establish a deadline by which the State must submit its annual report to the Secretary under proposed revised § 412.154(d)(2) of the regulations. We also are proposing the criteria that we would use to evaluate the State in order to determine whether or not the State would be exempted from the Hospital Readmissions Reduction Program beginning with FY 2014. In addition, we are proposing to define the ''base operating DRG payment amount'' for Maryland hospitals under § 412.152 of the regulations in the event that the State is not exempted from the Hospital Readmissions Reduction Program.

We are proposing that the State of Maryland must submit this preliminary report to CMS no later than January 15 of each year for CMS to consider, through the IPPS/LTCH PPS proposed rule for a Federal fiscal year, its exemption from the Hospital Readmissions Reduction Program for the upcoming Federal fiscal year. For example, the State of Maryland would have to submit the report by January 15, 2014 for consideration for the FY 2015 (beginning October 1, 2014) program year. This deadline would provide CMS sufficient time to evaluate the report, have any discussions with the State regarding its program, and prepare a presentation of that report for the IPPS/LTCH PPS proposed rule. Under this proposal, we also would require that the State submit a final report, with updated information on the State's readmissions program and updated cost savings and health outcomes information, to CMS no later than June 1 of each year in order for CMS to determine, through the IPPS/LTCH PPS final rule for a Federal fiscal year, whether the State meets the requirements for exemption from the Hospital Readmissions Reduction Program in that upcoming Federal fiscal year. As such, for FY 2015, under proposed § 412.154(d)(2)(ii), the State of Maryland would submit its preliminary report to the Secretary no later than January 15, 2014, and its final report to the Secretary no later than June 1, 2014, for consideration of exemption from the Hospital Readmissions Reduction Program.

For FY 2014, we have received a preliminary report from Maryland describing its readmissions program. Similar to its report submitted for FY 2013, Maryland described its current readmissions program, the Admissions-Readmission Revenue (ARR) Program. Under the voluntary program, the State pays hospitals under a case-mix adjusted bundled payment per episode of care, where the episode of care is defined as the initial admission and any subsequent readmissions to the same hospital or linked hospital system that occur within 30 days of the original discharge. According to the State, an initial admission with no readmissions provides the hospital with the same weight as an initial admission with multiple readmissions. Therefore, hospitals receive a financial reward for decreased readmissions (as determined through the case-mix adjusted episode of care weights). In the report, Maryland indicated that the reduction in intra-hospital readmission rates (that is, readmissions to the same hospital as the initial admission) resulted in approximately $25 million, or 0.27 percent, in savings to the participating hospitals for 2011 and 2012. In addition, Maryland reported that its readmission rate per 1,000 Medicare beneficiaries declined from 17.14 percent (CY 2011, Quarter 2) to 15.21 percent (CY 2012, Quarter 2). The State also acknowledged in that report that it has begun to track inter-hospital readmissions, where a patient is admitted to one hospital and readmitted to another hospital, which is comparable to how readmissions are measured under the Hospital Readmissions Reduction Program. In the FY 2013 IPPS/LTCH PPS final rule, we estimated that, under the Hospital Readmissions Reduction Program, for FY 2013, Medicare IPPS operating payments would decrease by approximately $300 million (or 0.3 percent) of total Medicare IPPS operating payments. Maryland indicated that, for FY 2013, it would achieve comparable savings because it intends to reduce the rate update factor for all hospitals by 0.3 percent, regardless of a hospital's performance on readmissions.

Furthermore, in its FY 2014 preliminary report to the Secretary, the State of Maryland indicated that, for FY 2014, subject to approval by the Commission, it is proposing a shared savings approach, which would be applied to all hospitals in the State. Under that shared savings approach, hospitals in the State would be ranked based on their performance on readmissions, under which hospitals with high readmissions above an established standard would experience a reduction in their revenue and the hospitals below the established standard

would not experience a reduction in their revenue. For Maryland hospitals that are in the voluntary ARR program paid under the case-mix adjusted bundled payment per episode of care that are performing worse than the established standard for readmissions, their payment per episode of care would be reduced. In addition, the State proposes that hospitals that improve in readmissions above a certain standard would experience no reduction in their payments and those hospitals below the standard would experience a reduction. Based on this preliminary information, we believe that the State can achieve savings on readmissions that are tied to hospitals' performance on readmissions, which is comparable to the Hospital Readmissions Reduction Program applied throughout the rest of the country.

For FY 2014, we are proposing to evaluate Maryland based on whether, under the shared savings approach, it can achieve comparable health outcomes and cost savings to the Hospital Readmissions Reduction Program. We note that, for FY 2014, we project that the Hospital Readmissions Reduction Program will result in a 0.2 percent decrease, or approximately $175 million, in payments to hospitals. We are inviting public comments on this proposal.

In this proposed rule, we also are proposing to define ''base operating DRG payment amount'' for hospitals paid under section 1814(b)(3) of the Act in the event that we do not exempt Maryland hospitals from the Hospital Readmissions Reduction Program in a given year. Consistent with section 1886(q)(2) of the Act, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53382), under the regulations at § 412.152, we defined the ''base operating DRG payment amount'' under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments. As required by the statute, the definition of ''base operating DRG payment amount'' does not include adjustments or add-on payments for IME, DSH, outliers, and low-volume hospitals provided for under sections 1886(d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of the Act, respectively. Section 1886(q)(2) of the Act does not exclude new technology payments made under section 1886(d)(5)(K) of the Act in the definition of ''base operating DRG payment amount''; therefore, any payments made under section 1886(d)(5)(K) of the Act are included in the definition of ''base operating DRG payment amount.'' In addition, under the regulations at § 412.152, we define ''wage-adjusted DRG operating payment'' as the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii).

Acute care hospitals located in the State of Maryland currently are not paid under the IPPS but are, instead, paid under a special waiver as provided by section 1814(b)(3) of the Act. For these applicable hospitals, we are proposing that the term ''base operating DRG payment amount'' means the base operating DRG payment amount defined at § 412.152. In other words, we are proposing to revise existing § 412.152, to specify that, for Maryland hospitals, the ''base operating DRG payment amount'' is an amount equal to the IPPS wage adjusted DRG payment amount or the average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index plus new technology payments that would be paid to Maryland hospitals absent section 1814(b)(3) of the Act. Although Maryland hospitals are currently paid under this waiver and not under the IPPS, if Maryland is not exempt from the Hospital Readmissions Reduction Program in a given year, we are proposing that, to determine the amount by which the hospitals' payments under section 1814(b)(3) of the Act would be reduced under the Hospital Readmissions Reduction Program, the readmission payment adjustment under § 412.154(b) would be determined using the estimated base operating DRG payment amount that would have applied had the hospital been paid under the IPPS. To implement this policy, we are proposing that claims submitted by Maryland hospitals would be ''priced'' under the IPPS payment methodology, and if a Maryland hospital has a readmissions payment adjustment factor, that factor would be applied to that base operating DRG payment amount to determine the payment adjustment under § 412.154(b) (that is, the amount of the payment reduction). We are proposing that the amount of the payment reduction, if any, would be applied to (that is, subtracted from) the payments made to Maryland hospitals under the waiver. This proposed methodology would result in Maryland hospitals having the readmissions adjustment factor applied in a manner similar to that which is applied to hospitals that are paid under the IPPS.

Furthermore, we are proposing that if Maryland is not exempt from the Hospital Readmissions Reduction Program in a given year, the proposed definition of ''base operating DRG payment amount'' for Maryland hospitals discussed above (that is, the base operating DRG payment amount calculated as if the hospital were paid under the IPPS), and not any payment amount made under the waiver under by section 1814(b)(3) of the Act, would be used to calculate both the ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' (defined at § 412.152) for purposes of determining the hospital's readmission adjustment factor that accounts for excess readmissions under § 412.154(c). We are inviting public comments on this proposal.

e. Proposed Floor Adjustment Factor for FY 2014 (§ 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. . . .'' In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53386), we codified the calculation of this ratio 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 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years. We codified the floor adjustment factor at § 412.154(c)(2) of the regulations.

For FY 2013, under § 412.154(c), we specified that an applicable hospital will receive an adjustment factor that is either the greater of the ratio or a floor adjustment factor of 0.99. For FY 2014, we are proposing that the floor adjustment factor be 0.98, consistent with section 1886(q)(3) of the Act, as codified at § 412.154(c)(2). As finalized in the FY 2013 IPPS/LTCH PPS final rule, the ratio is rounded to the fourth decimal place. In other words, for FY 2014, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is

between 1.0 and 0.9800. We are inviting public comments on this proposal.

f. Proposed Applicable Period for FY 2014

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. We finalized our policy to use 3 years of claims data to calculate the readmission measures in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53390), 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 readmission 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.

For the Hospital Readmissions Reduction Program for FY 2013, we established an applicable period under § 412.152 as July 1, 2008, to June 30, 2011. Specifically, to calculate the excess readmission ratios and to calculate the payment adjustments for FY 2013 (including aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment), we used Medicare claims data from the 3-year time period of July 1, 2008 to June 30, 2011 (76 FR 51671 and 77 FR 53388).

In this proposed rule, consistent with the definition at § 412.152 of the existing regulations, we are proposing that the applicable period for FY 2014 under the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2009, to June 30, 2012. That is, we would determine the excess readmission 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 to June 30, 2012, as this is the most recent available 3-year period of data upon which to base these calculations. As discussed later in this section, although we are proposing an applicable period of July 1, 2009 through June 30, 2012 for FY 2014, for purposes of determining the proposed readmissions payment adjustment factors for this FY 2014 proposed rule, we are using excess readmission ratios based on older data, that is, from the FY 2013 applicable period of July 1, 2008 to June 30, 2011 (that includes the application of the proposed planned readmission algorithm discussed earlier in this section). However, for the FY 2014 final rule, we intend to use excess readmission ratios based on data from the applicable period of July 1, 2009 to June 30, 2012, if that period is finalized.

g. Proposed Refinements of the Methodology To Calculate the Aggregate Payments for Excess Readmissions

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. . . .'' In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), we defined ''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).

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 Readmission Ratio' . . . for such hospital for such applicable period minus 1.'' In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), we included this definition of ''aggregate payments for excess readmissions'' under the regulations at § 412.152.

The ''Excess Readmission Ratio'' is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmission 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 readmission 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.

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. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), we included this definition of ''aggregate payments for all discharges'' under the regulations at § 412.152.

We note that we are taking this opportunity to propose to make a technical change to the definition of ''basing operating DRG payment amount'' in the existing regulations at § 412.152 to reflect our policy that the difference between the applicable hospital-specific payment rate and the Federal payment rate for SCHs and MDHs is excluded from the base operating DRG amount for these hospitals. We note that section 1886(q)(2)(B)(i) of the Act provides ''special rules'' for MDHs with respect to discharges occurring during FYs 2012 and 2013, and not for subsequent years. Under current law, as discussed in section V.F. of the preamble of this proposed rule, the MDH program expires at the end of FY 2013 (that is, the MDH program is in effect through September 30, 2013); therefore, the technical change would reflect that our policy applies to MDHs for FY 2013 only.

As discussed above, when calculating the numerator (aggregate payments for excess readmissions), we determined 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 Readmission 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 that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) to calculate the excess readmission 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.

For FY 2014, we are proposing to use MedPAR claims with discharge dates that are on or after July 1, 2009, and no later than June 30, 2012. As specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), 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 2009 through FY 2012 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmission adjustment factors. Interested individuals may order these files through the Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on the MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and further 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.

For this FY 2014 proposed rule, we are proposing to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2009, and no later than June 30, 2012. However, we note that, for the purposes of modeling the proposed readmissions payment adjustment factors in this proposed rule, we used excess readmission ratios based on an older performance period of July 1, 2008 to June 30, 2011 with the application of the proposed planned readmission algorithm.

Consistent with the approach taken in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27964), for the purpose of modeling the proposed FY 2014 readmissions payment adjustment factors, we are using excess readmission ratios for applicable hospitals from the FY 2013 Hospital Readmission Reduction Program applicable period. For FY 2014, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2014 applicable period of July 1, 2009 to June 30, 2012 before they are made public under our policy regarding the reporting of hospital-specific information, which is discussed later in this section.

In this proposed rule, we are proposing for FY 2014 to use MedPAR data from July 1, 2009 through June 30, 2012, and we are using the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009 with discharges dates that are on or after July 1, 2009, the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010, the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2010, and the December 2012 update of the FY 2012 MedPAR file to identify claims within FY 2012 with discharge dates no later than June 30, 2012. For the FY 2014 IPPS/LTCH PPS final rule, we intend to use the same MedPAR files as listed above, with the exception of using the March 2013 update of the FY 2012 MedPAR file.

In order to identify the admissions for each condition for an individual hospital for calculating the aggregate payments for excess readmissions, as we did for FY 2013, we are proposing, for FY 2014, to identify each applicable condition using the same ICD–9–CM codes used to identify applicable conditions to calculate the excess readmission ratios. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669), in our discussion of the methodology of the readmissions measures, we stated that 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. 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 Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

In order to identify the applicable conditions to calculate the aggregate payments for excess readmissions, as we did for FY 2013, we are proposing, for FY 2014, to identify the claim as an applicable condition if the ICD–9–CM code for that condition is listed as the principal diagnosis on the claim, consistent with the methodology to identify conditions to calculate the excess readmission ratio. Based on public comments that we received on the FY 2013 IPPS/LTCH PPS proposed rule, which stated that the index admissions that are not considered readmissions for the purpose of the readmissions measures, and are thus excluded from the calculation of the excess readmission ratio, should also not be considered admissions for the purposes of determining a hospital's aggregate payments for excess readmissions, we are proposing to further modify our methodology to identify the admissions included in the calculation of ''aggregate payments for excess readmissions.'' As we did for FY 2013 in response to public comments (77 FR 53390), using our MedPAR data source, we identified admissions for the purposes of calculating aggregate payments for excess readmissions making the following exclusions: (1) Hospitalizations for patients discharged with an in hospital death; (2) hospitalization for patients discharged against medical advice; (3) transfers; (4) hospitalizations for patients under 65; (5) hospitalizations for patients enrolled in Medicare Part C; and (6) same day discharges for AMI cases. These admissions were excluded based on how they were identified in the MedPAR file.

For FY 2014, we are proposing to make the same exclusions as we did in FY 2013, but, for some of the exclusions, to identify them using a different methodology which is more consistent with the manner in which exclusions are made to the admissions used to calculate the excess readmission ratio. For FY 2014, in order to have the same types of admissions to calculate aggregate payments for excess readmissions, as is used to calculate the excess readmission ratio, we are proposing to identify admissions for the purposes of calculating aggregate payments for excess readmissions as follows; we note where our proposed methodology for exclusions for FY 2014 differs from our methodology in FY 2013:

- We would exclude admissions that are identified as an applicable condition based on the ICD–9–CM code listed as the primary diagnosis if the patient died in the hospital, as identified by the discharge status code on the MedPAR claim. This is consistent with how we identified patients who died in the

hospital in the FY 2013 IPPS/LTCH PPS final rule.

• We would exclude admissions identified as an applicable condition based on the ICD–9–CM code listed as the primary diagnosis for which the patient was transferred to another acute care hospital (that is, a CAH or an IPPS hospital), as identified through examination of contiguous stays in MedPAR at other hospitals. (We note that this proposed step differs from the methodology we used in the FY 2013 IPPS/LTCH PPS final rule to identify transfers based on discharge destination codes in the MedPAR file.)

• We would exclude admissions identified as an applicable condition based on the ICD–9–CM code listed as the primary diagnosis 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. (We note that this proposed step differs from the methodology we used in the FY 2013 IPPS/LTCH PPS Rule in that we previously used claims in the MedPAR file to identify a patient's age.)

• 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. (This is consistent with how we identified patients with same day discharges for AMI in the FY 2013 IPPS/LTCH PPS final rule. In addition, it is consistent with the calculation of the excess readmission ratio for AMI where same day discharges for AMI are not included as an index admission.)

Furthermore, we are proposing to 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 readmission ratios based solely on admissions and readmissions for Medicare FFS patients. For FY 2013, we had excluded admissions for Medicare Advantage patients based on whether the claim was identified as a Medicare Advantage claim in the MedPAR file or whether the FFS payment amount on the claim was for an IME payment only, also indicative of an admission for a Medicare Advantage patient. For FY 2014, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Enrollment Database, which is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmission ratios.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53390), we noted that there were additional exclusions to the admissions used to calculate the excess readmission ratio that we could not apply to the calculation of aggregate payments for excess readmissions at the time of rulemaking. However, we stated our intention to modify our systems to identify the additional exclusions in order to calculate the aggregate payments for excess readmissions in a manner that would be more consistent with the calculation of the excess readmission ratio. Thus, in addition to the exclusions to the admissions we finalized in the FY 2013, we are proposing additional exclusions so that the criteria used to identify admissions for the purposes of calculating aggregate payments for excess readmissions would be the same as the criteria used to identify admissions for the purposes of calculating the excess readmission ratios. We are proposing to link our MedPAR claims data with the Medicare Enrollment Database to make additional exclusions to the admissions used to calculate aggregate payments for excess readmissions, which is consistent with our established methodology for calculating of the excess readmission ratios. The Medicare Enrollment Database contains information on all individuals entitled to Medicare, including demographic information, enrollment dates, third party buy-in information, and Medicare managed care enrollment. For FY 2014, we are proposing to include the following additional steps to identify admissions for the purposes of calculating aggregate payments for excess readmissions:

• We are proposing to 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 are proposing to 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 are proposing to exclude all multiple admissions within 30 days of a prior index admission, 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 readmission ratio.

We are inviting public comments on these proposals.

The tables below list the ICD–9–CM codes we are proposing to use to identify each applicable condition to calculate the aggregate payments for excess readmissions under this proposal for FY 2014. These ICD–9–CM codes also will be used to identify the applicable conditions to calculate the excess readmission ratios, consistent with our policy finalized in the FY 2012 IPPS/LTCH PPS final rule. The list of ICD–9–CM codes for each condition has not changed from the list provided in the FY 2013 IPPS/LTCH PPS final rule.

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.

ICD–9–CM CODES TO IDENTIFY PNEUMONIA (PN) CASES—Continued

ICD–9–CM Code	Description of code
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.
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.

For FY 2014, we are proposing to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2009 to June 30, 2012, 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 exclusions for the types of admissions discussed above.

FORMULAS TO CALCULATE THE READMISSION ADJUSTMENT FACTOR

AGGREGATE PAYMENTS FOR EXCESS READMISSIONS = [sum of base operating DRG payments for AMI × (Excess Readmission Ratio for AMI–1)] + [sum of base operating DRG payments for HF × (Excess Readmission Ratio for HF–1)] + [sum of base operating DRG payments for PN × (Excess Readmission Ratio for PN–1)].

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).

Readmissions Adjustment Factor for FY 2014 is the higher of the ratio or 0.9800.

* Based on claims data from July 1, 2009 to June 30, 2012 for FY 2014.

h. Clarification of Reporting Hospital-Specific Information, Including Opportunity To Review and Submit Corrections

In the FY 2013 IPPS/LTCH PPS final rule, we finalized our policy for the public reporting of the information for this program as well as providing hospitals with an opportunity to review and submit corrections to the information prior to public reporting. We are not proposing changes to the reporting, review, and submittal of corrections policy and the regulatory text that we finalized in the FY 2013 IPPS/LTCH final rule (77 FR 53399 through 53401). However, we wish to clarify that requests to incorporate claims previously billed under a different CMS Certification Number (CCN) by recently acquired entities into calculations for a particular CCN will not be considered. This is because the particular CCN was not responsible for the patients under the other CCN prior to the hospital merger at the time of service.

In addition to public comments on the proposed refinements to the readmissions measures, the proposed expansion of the applicable conditions for FY 2015, and the proposed changes to the readmission payment adjustment factors, we welcome public comment on the impact of the Hospital Readmissions Reduction Program on hospitals, including ''safety net'' hospitals.

H. Hospital Value-Based Purchasing (VBP) Program

1. Statutory Background

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 Value-Based Purchasing (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.

Section 1886(o)(1)(B) of the Act states that the Hospital VBP Program applies to payments for hospital discharges occurring on or after October 1, 2012. In accordance with section 1886(o)(6)(A) of the Act, we are required to make value-based incentive payments under the Hospital VBP Program to hospitals that meet or exceed performance standards for a performance period for a fiscal year. As further required by section 1886(o)(6)(C)(ii)(I) of the Act, we base each hospital's value-based payment percentage on the hospital's Total Performance Score (TPS) for a specified performance period. In accordance with section 1886(o)(7) of the Act, the total amount available for value-based incentive payments for a fiscal year will be equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as estimated by the Secretary. For FY 2013, the available funding pool was equal to 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary, and the size of the applicable percentage will increase to 1.25 percent for FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

Section 1886(o)(1)(C) of the Act generally defines the term ''hospital'' for purposes of the Hospital VBP Program as a subsection (d) hospital (as that term is defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term ''hospital,'' with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the FY 2013 Hospital VBP Program

In April 2011, we issued the Hospital Inpatient VBP Program final rule to implement section 1886(o) of the Act (76 FR 26490 through 26547). As described more fully in that final rule, for the FY 2013 Hospital VBP Program, we adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) measure that we categorized into two domains (76 FR 26495 through 26511). We grouped the 12 clinical process-of-care measures into a clinical process of care domain, and placed the HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495), and performance standards on which hospital performance will be evaluated. To determine whether a hospital meets or exceeds the performance standards for these measures, we assessed each hospital's achievement during this specified performance period, as well as its improvement during this period as compared with its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We then calculated a TPS for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights were clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We converted each hospital's TPS into a value-based incentive payment percentage using a linear exchange function and then converted the value-based incentive payment percentage into a per discharge value-based incentive payment amount. We incorporated the reduction to each hospital's base operating DRG payment

amount for each discharge, as well as the value-based incentive payment amounts that the hospital earned as a result of its performance (if applicable) into our claims processing systems in January 2013, and these adjustments applied to FY 2013 discharges.

We finalized the Hospital VBP Program's payment adjustment calculation methodology, including codifying certain definitions related to the Program, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53569 through 53571). We also finalized our methodology for estimating the total amount available for value-based incentive payments in a fiscal year under the Hospital VBP Program (77 FR 53571 through 53573), our methodology to calculate the value-based incentive payment adjustment factor (77 FR 53573 through 53576), the delayed application of the base-operating DRG payment amount reduction for FY 2013 discharges until incorporation of the value-based incentive payment adjustments into our claims processing system (77 FR 53577), and our process for reducing the base-operating DRG payment amount and applying the value-based incentive payment adjustment for FY 2013 (77 FR 53577 through 53578).

We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614) for further explanation of the details of the FY 2013 Hospital VBP Program and our other finalized policies related to future fiscal years.

3. FY 2014 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 final rule for more details.

Under section 1886(o)(7)(c)(ii) of the Act, the applicable percent for the FY 2014 Hospital VBP Program is 1.25 percent. Based on the December 2012 update of the FY 2012 MedPAR file, we estimate that the total amount available for value-based incentive payments for FY 2014 is $1.1 billion. We intend to update this estimate for the final rule, using the March 2013 update of the FY 2012 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, as referenced above, we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor which will be applied to the base operating DRG payment amount for each discharge occurring in FY 2014, on a per-claim basis. Proxy value-based incentive payment adjustment factors may be found in Table 16 for this proposed rule (which is available on the CMS Web site). The proxy factors are based on the TPSs from the FY 2013 Hospital VBP Program. These FY 2013 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 the proxy value-based incentive payment adjustment factors is 1.8362446088. This slope, along with the estimated amount available for value-based incentive payments, may also be found in Table 16. We intend to include an update to this table, as Table 16A, in the final rule (which will be available on the CMS Web site), to reflect changes based on the December update to the FY 2012 MedPAR file. The updated proxy value-based incentive payment adjustment factors for FY 2014 will continue to be based on historic FY 2013 Program TPSs because hospitals will not have been given the opportunity to review and correct their actual FY 2014 value-based incentive payment adjustment factors for the FY 2014 VBP program until after the final rule is published. After hospitals have been given an opportunity to review and correct their actual value-based incentive payment adjustment factors for FY 2014, we will add a new table, Table 16B (which will be available 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 2014 Hospital VBP Program. We expect that Table 16B will be posted on the CMS Web site in October 2013.

4. FY 2014 Hospital VBP Program Measures

For FY 2014, we adopted 17 measures for the Hospital VBP Program, including the 12 clinical process of care measures and the HCAHPS measure that we adopted for the FY 2013 Hospital VBP Program, 1 new clinical process of care measure (SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate). The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP-Inf-9 is discussed in more detail in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74530).

Although we also previously adopted 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending per Beneficiary Measure for the FY 2014 Hospital VBP Program, we have suspended the effective dates of these measures, with the result that these measures will not be included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530). However, as discussed further below, we finalized adoption of a Medicare Spending per Beneficiary Measure and an AHRQ composite measure for the FY 2015 Hospital VBP Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592).

Set out below is a complete list of the measures we adopted for the FY 2014 Hospital VBP Program:

FINALIZED QUALITY MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction:	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.

FINALIZED QUALITY MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM—Continued

Measure ID	Measure description
Heart Failure:	
HF–1	Discharge Instructions.
Pneumonia:	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
Healthcare-associated infections:	
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP–Inf–9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2.
Surgeries:	
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience of Care Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey*.
Outcome Measures	
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate.
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate.
MORT–30 PN	Pneumonia (PN) 30-Day Mortality Rate.

*The finalized dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions that we adopted for the FY 2013 Hospital VBP Program.

5. FY 2015 Hospital VBP Program Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592), we adopted 12 Clinical Process of Care measures, one Patient Experience of Care measure in the form of the HCAHPS survey, 5 Outcome measures, including three 30-day mortality measures, the AHRQ PSI composite measure, and the CLABSI measure, and one Efficiency measure for the FY 2015 Hospital VBP Program.

We did not adopt two clinical process measures (SCIP–Inf–10 and AMI–10) that we determined were ''topped-out'' according to our criteria finalized in the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497). We also did not adopt SCIP–VTE–1 for the FY 2015 Hospital VBP Program because we believed that the measure is very similar to another measure we have adopted for the Program (SCIP–VTE–2) and, in our view, is not as closely linked to better surgical outcomes because it assesses the ordering of VTE prophylaxis, rather than the patient's actual receipt of such prophylaxis within 24 hours of surgery. We also noted that, during a recent maintenance review of SCIP–VTE–1, the National Quality Forum (NQF) concluded that it would no longer endorse this measure.

Set out below is a complete list of the measures we adopted for the FY 2015 Hospital VBP Program:

FINALIZED QUALITY MEASURES FOR FY 2015 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Clinical Process of Care Measures	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
HF–1	Discharge Instructions.
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.
SCIP–Card–2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.

FINALIZED QUALITY MEASURES FOR FY 2015 HOSPITAL VBP PROGRAM—Continued

Measure ID	Measure description
Patient Experience Measures	
HCAHPS *	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.
Outcome Measures	
AHRQ PSI composite	Complication/patient safety for selected indicators (composite).
CLABSI	Central Line-Associated Blood Stream Infection.
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate.
MORT–30–HF	Heart Failure (HF) 30-day mortality rate.
MORT–30–PN	Pneumonia (PN) 30-day mortality rate.
Efficiency Measures	
MSPB–1	Medicare Spending per Beneficiary.

* Dimensions of the HCAHPS survey for use in the FY 2015 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions of the HCAHPS survey that have been finalized for prior Hospital VBP Program years.

6. FY 2016 Hospital VBP Program Measures

a. Measures Previously Adopted and Proposal To Remove AMI–8a, PN–3b, and HF–1

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592 through 53593), we adopted for the FY 2016 Hospital VBP Program the three 30-day mortality measures that we had finalized for the Hospital VBP Program for FYs 2014 and 2015. We also adopted the AHRQ patient safety composite (PSI–90) for the Hospital VBP Program for FY 2016. We adopted those measures at that time in order to adopt a longer performance period and collect more data for performance scoring than would be possible if we waited to make those proposals until this proposed rule. We also adopted those measures at that time because we recognized that under section 1886(o)(3)(C) of the Act, we must establish and announce performance standards not later than 60 days prior to the beginning of the performance period for the fiscal year involved. We also automatically readopted the remaining FY 2015 measures (with the exception of the CLABSI measure), in accordance with our policy of automatic readoption of measures (77 FR 53592).

In this proposed rule, we are proposing to remove three measures from the measure set previously adopted that we have discussed above. First, we analyzed the clinical process of care measures for ''topped out'' status and concluded that AMI–8a: Primary PCI Received within 90 Minutes of Hospital Arrival is ''topped-out.'' Our methodology for evaluating whether a measure is topped-out focuses on two criteria: (1) National measure data show statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) national measure data show a truncated coefficient of variation (TCV) less than 0.10. We believe that topped-out measures should not be included in the Hospital VBP Program because measuring hospital performance on those measures has no meaningful effect on a hospital's TPS. Therefore, we are proposing to remove AMI–8a from the FY 2016 Hospital VBP Program measure set.

We welcome public comments on our proposal to remove AMI–8a from the FY 2016 Hospital VBP Program measure set and on whether any other existing Hospital VBP Program measures are topped-out and, therefore, should be removed from the previously adopted FY 2016 measure set. We intend to update our topped-out analysis using the most recently available data and will announce in the FY 2014 IPPS/LTCH PPS final rule whether any of the other FY 2016 measures will be removed due to topped-out status.

Second, we are proposing to remove PN–3b, Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital, and HF–1, Discharge Instructions, from the FY 2016 Hospital VBP Program. Both PN–3b and HF–1 are no longer endorsed by the NQF, and we note that in its 2013 Pre-Rulemaking Report, the Measure Applications Partnership (MAP) did not recommend those measures for use in the Hospital VBP Program.

As of February 28, 2012, the NQF Pneumonia Thoracic CT Work Group of the Pulmonary and Critical Care Endorsement Maintenance Project believed there was insufficient evidence that performing blood cultures prior to initiation of antibiotics led to better outcomes. The workgroup also cited significant issues with documentation of the timing of the blood cultures with respect to the initiation of the antibiotics. Documentation is often done retrospectively providing opportunities for data entry errors. The issue is compounded with EHRs as data entry is electronically time-stamped and may not accurately indicate when blood cultures were drawn or antibiotics given. Although the measure is currently ''chart-abstracted,'' the data might be abstracted from an EHR, instead of from a paper record.

We note further that NQF reviewed HF–1 during the summer of 2012. The NQF Steering Committee determined that there was insufficient evidence to link the HF–1 measure of discharge instructions with better outcomes. The committee noted that discharge instructions, as measured by HF–1, did not cover several important issues, including patient understanding of the instructions and their appropriateness for patients' education and literacy levels.

Therefore, we do not believe that these measures appropriately capture relevant inpatient quality information for purposes of the Hospital VBP Program, and, as indicated above, we are proposing to remove them from the FY 2016 program.

b. Proposed New Measures for the FY 2016 Hospital VBP Program

We considered if we should adopt additional measures for the FY 2016 Hospital VBP Program. We considered what measures are eligible for adoption based on the statutory requirements, including specification under the Hospital IQR Program and posting dates on the *Hospital Compare* Web site, as

well as our priorities for quality improvement as outlined in the National Quality Strategy, which is available for download at *http://www.healthcare.gov/news/reports/nationalqualitystrategy032011.pdf*.

We believe the following measures meet the statutory requirements for inclusion in the Hospital VBP Program. We also believe that these measures represent important components of quality improvement in the acute inpatient hospital setting.

Influenza Immunization (IMM–2, NQF #1659) is a chart-abstracted prevention measure that addresses acute care hospitalized inpatients age 6 months or older that were screened for seasonal influenza immunization status and were vaccinated prior to discharge, if indicated. We believe this measure is important to quality improvement efforts because about 36,000 adults die and over 200,000 are hospitalized annually for flu-related causes. Older adults are more vulnerable to influenza, and adults over age 65 comprise about 90 percent of deaths related to flu. Vaccinations can significantly reduce the number of flu-related illnesses and deaths.

This measure was incorporated into the Hospital IQR Program for FY 2014 in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50211), and data collection began with January 1, 2012 discharges. Measure data were posted on *Hospital Compare* on December 13, 2012, and MAP supported its inclusion in the Hospital VBP Program in its February 2013 report (available at *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), noting that it addresses a high-impact condition not adequately addressed in the program's current measure set. Therefore, we are proposing to adopt IMM–2 into the Clinical Process of Care domain for the FY 2016 Hospital VBP Program.

Catheter-Associated Urinary Tract Infection (CAUTI, NQF #0138) is an HAI measure reported via CDC's National Healthcare Safety Network (NHSN). This measure is important to quality improvement efforts because the urinary tract is the most common site of HAIs, accounting for more than 30 percent of infections reported by acute care hospitals. Complications associated with CAUTI cause discomfort to patients, prolonged hospitals stays, and increased costs and mortality. More than 13,000 deaths each year are associated with UTIs.

This measure was finalized for the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51617 through 51618), and data collection began with January 1, 2012 discharges. Measure data were posted on *Hospital Compare* on December 13, 2012, and MAP supported its inclusion in the Hospital VBP Program in its February 2013 report, noting that it addresses the National Quality Strategy (NQS) priorities not adequately addressed in the program's current measure set. Therefore, we are proposing to adopt the NHSN CAUTI measure into the Outcome domain for the FY 2016 Hospital VBP Program.

Surgical Site Infection (SSI, NQF #0753) is an HAI measure reported via CDC's NHSN. As currently specified under the Hospital IQR Program, the measure is restricted to colon procedures, including incision, resection, or anastomosis of the large intestine, and large-to-small and small-to-large bowel anastomosis, and abdominal hysterectomy procedures, including those done by laparoscope. The measure is reported separately on *Hospital Compare* for those two surgery sites, and does not include rectal operations.

This measure was incorporated into the Hospital IQR Program in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50211), and data collection began with January 1, 2012 discharges. Measure data were posted on *Hospital Compare* on December 13, 2012, and MAP supported its inclusion in the Hospital VBP Program in its February 2013 report, noting that it addresses NQS priorities not adequately addressed in the program's current measure set. The SSI measure was stratified by surgery site when it was adopted for the Hospital IQR Program, and is both collected and publicly reported as a stratified measure. However, because we adopted SSI as one measure under the Hospital IQR Program, we are proposing to score the measure for purposes of the Hospital VBP Program as a weighted average of the measure's strata by applicable cases per stratum. Under this proposed scoring methodology, if a hospital meets the Hospital IQR Program's threshold for public display of its SSI measure strata scores during a Hospital VBP performance period—that is, at least one predicted infection during the applicable time period—we will calculate a weighted average of the measure's strata to score under the Hospital VBP Program.

We believe this proposal enables us to score participating hospitals on the underlying components of the SSI measure fairly. We note further that, for purposes of calculating performance standards displayed subsequently, we will equally weight the SSI measure's strata. We seek public comments on our proposed adoption of this measure and its proposed scoring methodology under the Hospital VBP Program.

We adopted the NHSN-based CLABSI measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53583), and refer readers to that regulation for further discussion of the measure. We continue to believe that the CLABSI measure is consistent with the Hospital VBP Program's statutory requirement that we consider measures of HAIs for the FY 2013 Hospital VBP Program's measure set. We also note that the measure was included in the HHS Action Plan to Prevent HAIs, which is referenced in section 1886(o)(2)(B)(i)(I)(ee) of the Act.

In the FY 2013 IPPS/LTCH PPS final rule, we stated that we would not automatically readopt CLABSI for the FY 2016 Program (77 FR 53592), although we stated our intent to adopt the measure in the future. We did not automatically readopt CLABSI because we understood that CDC was planning to submit a revised version of this measure to NQF for endorsement, and that there may have been substantive changes to the measure associated with reliability adjustment to the standardized infection ratio.

The reliability-adjusted standardized infection ratio (SIR) is an outcome measure that summarizes the healthcare-associated infection experience by type of infection (for example, central-line associated bloodstream infection, surgical site infection) for individual hospitals. The reliability-adjusted measure enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposures to medical devices or procedures (for example, central line-days, surgical procedure volume), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation in outcomes between hospitals. Accounting for these sources of variability enables better measure discrimination between hospitals and leads to more reliable quality measurements.

We are aware that the CDC has submitted the reliability-adjusted version of the CLABSI measure to the NQF for endorsement. We note further that, in its February 2013 report, MAP recommended adoption of the reliability-adjusted CLABSI measure ''contingent on NQF endorsement,'' and noted that the ''most recent NQF-endorsed version should be applied.'' We believe that our proposal to adopt the current CLABSI measure is consistent with this recommendation, and we intend to consider adopting the

reliability-adjusted CLABSI measure in future rulemaking.

We intend to monitor CDC's activity on this measure, particularly as it moves toward reliability adjustment, and intend to adopt the revised measure in future program years. However, in the absence of NQF endorsement of the reliability-adjusted measure, unless and until the Hospital IQR Program adopts the reliability adjustments, we are proposing to adopt the CLABSI measure as it currently exists into the Outcome domain for the FY 2016 Hospital VBP Program.

Below is a table that describes the measures for the FY 2016 Hospital VBP Program that we previously adopted, as well as the new measures that we are proposing to adopt.

PROPOSED AND READOPTED MEASURES FOR THE FY 2016 HOSPITAL VBP PROGRAM

Clinical Process of Care Measures	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
IMM–2**	Influenza Immunization.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6 a.m. Postoperative Serum Glucose.
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.
Outcome Measures	
CAUTI**	Catheter-Associated Urinary Tract Infection.
CLABSI***	Central Line-Associated Blood Stream Infection.
MORT–30–AMI*	Acute Myocardial Infarction (AMI) 30-day mortality rate.
MORT–30–HF*	Heart Failure (HF) 30-day mortality rate.
MORT–30–PN*	Pneumonia (PN) 30-day mortality rate.
PSI–90*	Complication/patient safety for selected indicators (composite).
SSI**	Surgical Site Infection. • Colon. • Abdominal Hysterectomy.
Efficiency Measures	
MSPB–1	Medicare Spending per Beneficiary.

* Measures previously finalized for the FY 2016 Hospital VBP Program.
** Proposed new measures.
*** Measures finalized for FY 2015 but not subject to immediate readoption.

We are inviting public comments on this measure set.

We also seek public comment on our intent to adopt the Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures for the FY 2017 Hospital VBP Program. Both of these measures are high-priority HAI measures listed in the HHS Action Plan to Prevent HAIs. We anticipate posting performance data for these measures on *Hospital Compare* later this year, and anticipate proposing to adopt these measures for the Hospital VBP Program in the FY 2015 IPPS/LTCH PPS proposed rule.

c. Future Measures for the Efficiency Domain

We are considering including additional measures in the Efficiency Domain for future years of both the Hospital IQR Program and the Hospital VBP Program. If we were to expand the Efficiency Domain in the future, we would do so through future rulemaking and in accordance with the requirements of section 1886(o) of the Act.

We are considering adding a measure of hospitals' performance on treating Medicare beneficiaries appropriately as a hospital inpatient or a hospital outpatient. Specifically, we are considering constructing a measure to assess the rate and/or dollar amount of billing hospital inpatient services to Medicare Part B, subsequent to the denial of a Part A hospital inpatient claim. We are considering such a measure in light of our recent proposal that when a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was determined not to be reasonable and necessary, or when a hospital determines under § 482.30(d) or § 485.641 after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary, the hospital may be paid for all of the Part B services that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient, if the beneficiary is enrolled in Medicare Part B (78 FR 16632 through 16646). We are inviting public comments on this or other approaches to include a measure of appropriateness of hospital inpatient services in future years of the Hospital IQR Program and the Efficiency Domain for the Hospital VBP Program.

We also are considering the addition of Medicare spending measures specific to physician services such as Radiology, Anesthesiology, and Pathology that

occur during a hospital stay. We are inviting public comment on how to best to construct measures of Medicare spending for these or other physician services provided during a hospital stay, for future inclusion in the Hospital IQR Program and the Efficiency Domain in the Hospital VBP Program.

7. Proposed Performance Periods and Baseline Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

b. Proposed Clinical Process of Care Domain Performance Period and Baseline Period for the FY 2016 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53594 through 53595), we finalized a 12-month performance period for FY 2015 Clinical Process of Care measures of CY 2013, or January 1, 2013 through December 31, 2013, with a corresponding baseline period of CY 2011, or January 1, 2011 through December 31, 2011, for purposes of calculating improvement points and performance standards. As we stated in that rule, a 12-month performance period provides us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders. We also noted that a 12-month performance period is consistent with the reporting periods used for these measures under the Hospital IQR Program.

We are proposing to adopt a 12-month performance period for FY 2016 Clinical Process of Care measures of CY 2014, or January 1, 2014 through December 31, 2014, for the FY 2016 Hospital VBP Program. We also are proposing to adopt a corresponding 12-month baseline period of CY 2012, or January 1, 2012 through December 31, 2012, for purposes of calculating improvement points and calculating performance standards.

We are inviting public comment on these proposals.

c. Proposed Experience of Care Domain Performance Period and Baseline Period for the FY 2016 Hospital VBP Program

Consistent with our goal of adopting a full 12-month period for this domain in order to collect a larger amount of HCAHPS survey data compared to a 9-month period, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53595), we finalized a 12-month performance period for FY 2015 Patient Experience of Care measures of CY 2013, or January 1, 2013 through December 31, 2013, with a corresponding baseline period of CY 2011, or January 1, 2011 through December 31, 2011, for purposes of calculating improvement points and performance standards. As we stated in that rule, a 12-month performance period provides us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders.

We are proposing to adopt a 12-month performance period for FY 2016 Patient Experience of Care measures of CY 2014, or January 1, 2014 through December 31, 2014, for the FY 2016 Hospital VBP Program. We also are proposing to adopt a corresponding 12-month baseline period of CY 2012, or January 1, 2012 through December 31, 2012, for purposes of calculating improvement points and calculating performance standards.

We are inviting public comment on these proposals.

d. Proposed Efficiency Domain Measure Performance Period and Baseline Period for the FY 2016 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53595 through 53596), we finalized a performance period for the Medicare Spending per Beneficiary measure for the FY 2015 Hospital VBP Program of May 1, 2013 through December 31, 2013, with a corresponding baseline period of May 1, 2011 through December 31, 2011. We finalized that performance period based on the measure's posting date on *Hospital Compare,* our desire to ensure consistency across domains where possible, and in order to ensure that data have been posted for at least 1 year prior to the beginning of the measure performance period.

In order to expand the dataset available for performance scoring on this measure, we are proposing to adopt a 12-month performance period for the Medicare Spending per Beneficiary measure for the FY 2016 Hospital VBP Program of CY 2014, or January 1, 2014 through December 31, 2014, with a corresponding baseline period of CY 2012, or January 1, 2012 through December 31, 2012. These proposed performance and baseline periods align with the performance and baseline periods for Clinical Process of Care Domain measures. These proposed performance and baseline periods also enable us to collect sufficient measure data, while allowing time to calculate and incorporate Medicare spending per Beneficiary measure data into the Hospital VBP Program scores in a timely manner.

We are inviting public comments on the proposed performance and baseline periods for the Medicare Spending per Beneficiary measure.

Proposed baseline and performance periods for FY 2016 (with the exception of the Outcome domain, discussed further below) are summarized in the following table.

PROPOSED PERFORMANCE AND BASELINE PERIODS FOR THE FY 2016 HOSPITAL VBP PROGRAM—CLINICAL PROCESS OF CARE, PATIENT EXPERIENCE OF CARE, AND EFFICIENCY DOMAINS

Domain	Baseline period	Performance period
Clinical Process of Care	January 1, 2012–December 31, 2012	January 1, 2014–December 31, 2014.
Patient Experience of Care	January 1, 2012–December 31, 2012	January 1, 2014–December 31, 2014.
Efficiency	January 1, 2012–December 31, 2012	January 1, 2014–December 31, 2014.

e. Proposed Outcome Domain Performance Periods and Baseline Periods for the FY 2017 through FY 2019 Hospital VBP Programs

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53598 through 53599) we finalized performance periods and baseline periods for the FY 2016 mortality and AHRQ PSI composite measures. These periods are summarized in the table below.

FINALIZED FY 2016 PERFORMANCE PERIODS AND BASELINE PERIODS FOR 30-DAY MORTALITY AND AHRQ PSI MEASURES

Measure	Baseline period	Performance period
Mortality	October 1, 2010–June 30, 2011	October 1, 2012–June 30, 2014.
AHRQ PSI composite	October 15, 2010–June 30, 2011	October 15, 2012–June 30, 2014.

In light of the time needed to process measure data for the three 30-day mortality and AHRQ PSI composite measures and our policy goal to collect enough data to generate the most reliable scores possible, we are proposing in this proposed rule to adopt performance periods for the three 30-day mortality and AHRQ PSI composite measures for the FY 2017 through FY 2019 program years. We also seek to increase transparency about performance of the Hospital VBP Program measures through use of *Hospital Compare* as a monitoring tool for hospitals to assess their performance on the Hospital VBP Program measures. We believe that aligning the Hospital VBP Program performance periods with the Hospital IQR Program reporting period duration would allow hospitals to review *Hospital Compare* measure rates when they are updated and incorporate this information into their quality improvement efforts, rather than having to wait until the Hospital VBP Program provides its scoring reports to hospitals. Further, we believe that aligning the Hospital IQR Program and the Hospital VBP Program in this manner will minimize the burden on participating hospitals by aligning the time periods during which they must monitor their performance on these measures.

Therefore, we are proposing to adopt the following performance and baseline periods for the three 30-day mortality and AHRQ PSI composite measures for the FY 2017 through FY 2019 Hospital VBP Programs. We note that the performance periods proposed below for the AHRQ PSI composite measure reach 24 months at their maximum, compared to the 36 months proposed for the 30-day mortality measures. We are proposing those durations for the AHRQ PSI measure in order to adopt performance periods that align with AHRQ's recommended data period for public reporting.

PROPOSED PERFORMANCE AND BASELINE PERIODS FOR 30-DAY MORTALITY AND AHRQ PSI COMPOSITE MEASURES

Domain	Baseline period	Performance period
FY 2017 Hospital VBP Program		
Outcome		
• Mortality	• October 1, 2010–June 30, 2012	• October 1, 2013–June 30, 2015.
• AHRQ PSI	• October 1, 2010–June 30, 2012	• October 1, 2013–June 30, 2015.
FY 2018 Hospital VBP Program		
Outcome		
• Mortality	• October 1, 2009–June 30, 2012	• October 1, 2013–June 30, 2016.
• AHRQ PSI	• July 1, 2010–June 30, 2012	• July 1, 2014–June 30, 2016.
FY 2019 Hospital VBP Program		
Outcome		
• Mortality	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
• AHRQ PSI	• July 1, 2010–June 30, 2012	• July 1, 2015–June 30, 2017.

We are inviting public comments on our proposal to adopt performance periods and corresponding baseline periods for these measures for the FY 2017 through FY 2019 Hospital VBP Programs.

8. Proposed Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced 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. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513).

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 codified our interpretation of the Hospital VBP statute with respect to performance standards in our regulations at § 412.165.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53599 through 53604), we adopted performance standards for FY 2015 and FY 2016 Hospital VBP Program measures. We also finalized our policy to update performance periods and performance standards for future Hospital VBP Program years via notice on our Web site or another publicly available Web site.

b. Performance Standards for the FY 2016 Hospital VBP Program Measures

We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for a detailed discussion of the methodology we adopted for calculating performance standards with respect to the clinical process of care, patient experience of care, and outcome measures, and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) for a discussion of the methodology we adopted for the Medicare Spending per Beneficiary measure. We have defined the ''achievement threshold'' as the median, or 50th percentile, of all hospitals' performance on a measure during a baseline period (or during the performance period in the case of the Medicare Spending per Beneficiary measure) with respect to a fiscal year (42 CFR 412.160). We are proposing to revise this definition, in order to clarify that while this is true for the majority of Hospital VBP Program measures, it does not apply to the Medicare Spending per Beneficiary measure. The performance standards for the Medicare Spending per Beneficiary measure are based on performance period data, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51655). Accordingly, we are proposing to revise the definition of ''achievement threshold'' at § 412.160 to read: ''Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the median (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.'' We welcome public comments on this proposed regulation text change.

We have defined the ''benchmark'' as the arithmetic mean of the top decile of all hospitals' performance on a measure during the baseline period (§ 412.160). Similar to the codified definition of ''achievement threshold'' above, this definition of ''benchmark'' does not apply to the Medicare Spending per Beneficiary measure. We are proposing to revise the definition of ''benchmark'' at § 412.160 to read: ''Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.'' The ''improvement threshold'' is an individual hospital's performance level on a measure during the baseline period with respect to a fiscal year,'' and that definition applies to all measures.

We continue to believe that the finalized methodology for calculating performance standards is appropriate for the Hospital VBP Program, and we recognize that we have an obligation to calculate the numerical values for each of these standards accurately. However, we also are concerned that if we display the numerical values of the performance standards in a particular rulemaking document, but then discover that we made a data or calculation error, the result might be that hospitals are held to inaccurate performance standards. Examples of the types of errors that could occur are inaccurate variables on Medicare claims, programming errors excluding hospitals that should have been included from performance standards calculations, or other errors that result in inaccuracies. For example, if our quality measurement software incorrectly excluded a number of hospitals from a given measure's performance standards calcluation, the resulting achievement thresholds and benchmarks could force participating hospitals to meet inaccurate performance standards, which could have unpredictable effects on hospitals' scores.

We also are aware that hospitals rely on the performance standards that we publicly display in order to target quality improvement efforts, and do not believe that it would be fair to participating hospitals to update repeatedly our finalized performance standards if we were to identify multiple errors.

We believe that the best method to balance our obligation to publicly display accurate performance standards with the need to correct such performance standards if we subsequently discover data errors is to make a single correction to a given measure's performance standards for a fiscal year. Under this proposed policy, if we identified data problems, calculation issues, or other errors with a significant impact on performance standards, we would have the ability to update the measure's performance standards once for a fiscal year.

Therefore, we are proposing to interpret the finalized definitions of ''achievement threshold'' and ''benchmark'' found under § 412.160 to not include the numerical values that result when the performance standards are calculated. Further, we are proposing to update a measure's performance standards for a fiscal year once if we identify data issues, calculation errors, or other problems that would significantly change the displayed performance standards. However, as has been our practice, and to remain fully transparent with participating hospitals, we intend to continue to display the performance standards' numerical values in rulemaking.

We finalized FY 2016 performance standards for the three 30-day mortality measures and the AHRQ PSI composite measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53603) and are displaying them again in the first table below. The numerical values for the proposed FY 2016 performance standards for the clinical process, outcome, and efficiency measures appear in the second table below, while numerical values for the proposed FY 2016 performance standards for the patient experience of care (HCAHPS survey) measure appear in the third table below. We note that the numerical values for the performance standards displayed below represent estimates based on the most recently-available data. We intend to update the numerical values in the FY 2014 IPPS/LTCH PPS final rule. Because the Medicare Spending per Beneficiary measure's performance standards are based on performance period data, we are unable to provide numeric equivalents for the standards at this time. For information purposes, during the period of May 1, 2011 through December 31, 2011, the achievement threshold would have been a Medicare Spending per Beneficiary ratio of 0.99, which corresponds to a standardized, risk-adjusted Medicare Spending per Beneficiary amount of $18,079, and the benchmark would have been 0.82, which corresponds to a Medicare Spending per Beneficiary amount of $14,985. We also note that the performance standards for the NHSN-based CLABSI, CAUTI, and SSI measures, the AHRQ PSI composite measure, and the Medicare Spending per Beneficiary measure are calculated with lower values representing better performance, in contrast to other measures, on which higher values indicate better performance. As discussed above, the performance standards displayed below for SSI are an equally weighted average of the measure's strata.

FINALIZED PERFORMANCE STANDARDS FOR CERTAIN FY 2016 HOSPITAL VBP PROGRAM OUTCOME DOMAIN MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.847472	0.862371
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.881510	0.900315
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.882651	0.904181
PSI–90	Complication/patient safety for selected indicators (composite)	0.622879	0.451792

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2016 HOSPITAL VBP PROGRAM CLINICAL PROCESS OF CARE, OUTCOME, AND EFFICIENCY DOMAIN MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Clinical Process of Care Measures			
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.	0.88625	1.00000
IMM–2	Influenza Immunization	0.89947	0.99036
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.	0.96429	1.00000
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.	0.98942	1.00000
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients	0.98951	1.00000
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.	0.97971	1.00000
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Post-operative Serum Glucose.	0.96797	0.99977
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.	0.96743	1.00000
SCIP–Card–2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.	0.97561	1.00000
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.98086	1.00000
Outcome Measures			
CAUTI	Catheter-Associated Urinary Tract Infection	0.826	0.000
CLABSI	Central Line-Associated Blood Stream Infection	0.473	0.000
SSI	Surgical Site Infection	0.737	0.000
Efficiency Measures			
MSPB–1	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.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2016 HOSPITAL VBP PROGRAM PATIENT EXPERIENCE OF CARE DOMAIN

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	53.33	77.59	85.98
Communication with Doctors	61.22	80.33	88.59
Responsiveness of Hospital Staff	36.44	64.65	79.72
Pain Management	47.93	70.16	78.24
Communication about Medicines	42.23	62.28	72.67
Hospital Cleanliness & Quietness	42.16	64.93	79.12

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2016 HOSPITAL VBP PROGRAM PATIENT EXPERIENCE OF CARE DOMAIN—Continued

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Discharge Information	62.85	84.45	90.26
Overall Rating of Hospital	36.45	69.05	83.89

We are inviting public comments on these proposed performance standards.

c. Certain Performance Standards for the FY 2017, FY 2018, and FY 2019 Hospital VBP Programs

We are proposing to adopt the following performance standards for the three 30-day mortality and AHRQ PSI composite measures for the FY 2017, FY 2018, and FY 2019 Hospital VBP Program years:

PROPOSED PERFORMANCE STANDARDS FOR THE THREE 30-DAY MORTALITY AND AHRQ COMPOSITE MEASURES FOR THE FY 2017 HOSPITAL VBP PROGRAM

Measure ID	Description	Achievement threshold	Benchmark
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.851458	0.871669
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.881794	0.903985
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.882986	0.908124
PSI–90	Complication/patient safety for selected indicators (composite)	0.580808	0.399880

PROPOSED PERFORMANCE STANDARDS FOR THE THREE 30-DAY MORTALITY AND AHRQ COMPOSITE MEASURES FOR THE FY 2018 HOSPITAL VBP PROGRAM

Measure ID	Description	Achievement threshold	Benchmark
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.850916	0.873053
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.883421	0.907656
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.882860	0.907900
PSI–90	Complication/patient safety for selected indicators (composite)	0.585397	0.400502

PROPOSED PERFORMANCE STANDARDS FOR THE THREE 30-DAY MORTALITY AND AHRQ COMPOSITE MEASURES FOR THE FY 2019 HOSPITAL VBP PROGRAM

Measure ID	Description	Achievement threshold	Benchmark
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.850671	0.873263
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.883472	0.908094
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.882334	0.907906
PSI–90	Complication/patient safety for selected indicators (composite)	0.585397	0.400502

We are inviting public comments on these proposed performance standards.

9. Proposed FY 2016 Hospital VBP Program Scoring Methodology

a. Proposed General Hospital VBP Program Scoring Methodology

In the Hospital Inpatient VBP Program final rule, we adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures. As noted in that rule, this methodology outlines an approach that we believe is well understood by patient advocates, hospitals, and other stakeholders because it was developed during a lengthy process that involved

extensive stakeholder input, and was based on a scoring methodology we presented in a report to Congress. We also noted in that final rule that we had conducted extensive additional research on a number of other important methodology issues to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for reasons of simplicity, transparency, and consistency, it is important to score hospitals using the same general methodology each year, with appropriate modifications to accommodate new domains and measures. We finalized a scoring methodology for the Medicare Spending per Beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 28087), for the FY 2015 Hospital VBP Program, we finalized our proposal to use these same scoring methodologies to score hospital performance for the FY 2015 Hospital VBP Program. In that rule, we stated that we believe these scoring methodologies continue to appropriately capture hospital quality as reflected by the finalized quality measure sets. We also noted that readopting the finalized scoring methodology from prior program years represents the simplest and most consistent policy for providers and the public.

We continue to believe that the finalized scoring methodology for the Hospital VBP Program is well understood by patient advocates, hospitals, and other stakeholders because it was developed during a lengthy process that involved extensive stakeholder input, and was based on a scoring methodology we presented in a report to Congress. As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53604), we believe that, for reasons of simplicity, transparency, and consistency, it is important to score hospitals using the same general methodology each year, with appropriate modifications to accommodate new domains and measures.

Therefore, we are proposing to readopt the finalized scoring methodology adopted for the FY 2015 Hospital VBP Program for the FY 2016 Hospital VBP Program. We welcome public comments on this proposal.

b. Proposed Domain Weighting for the FY 2016 Hospital VBP Program for Hospitals That Receive a Score on All Domains

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592), we added the Efficiency domain to the Hospital VBP Program beginning with the FY 2015 Hospital VBP Program. We also finalized our proposal for the following domain weights for the FY 2015 Hospital VBP Program for hospitals that receive a score on all four proposed domains (77 FR 53605 through 53606):

FINAL DOMAIN WEIGHTS FOR THE FY 2015 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL PROPOSED DOMAINS

Domain	Weight (percent)
Clinical Process of Care	20
Patient Experience of Care	30
Outcome	30
Efficiency	20

We stated that we believed this domain weighting appropriately reflects our priorities for quality improvement in the inpatient hospital setting and begins aligning with the National Quality Strategy's priorities. We believe that the domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the weighting places the strongest relative emphasis on outcomes and the patient experience, which we view as two critical components of quality improvement in the inpatient hospital setting. We further note that the domain weighting, for the first time, incorporates a measure of efficiency and continues to provide substantial weight to clinical processes.

As we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below.

We believe that the proposed domain weighting specified below will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the proposed domain weighting places the highest relative weight on measures of outcomes and continues to place significant weight on the patient experience and on efficiency, while maintaining clinical processes as an important component of the program's quality measurement.

Therefore, we are proposing the following domain weighting for the FY 2016 Hospital VBP Program:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2016 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL PROPOSED DOMAINS

Domain	Weight (percent)
Clinical Process of Care	10
Patient Experience of Care	25
Outcome	40
Efficiency	25

We welcome public comments on this proposed domain weighting.

c. Proposed Domain Weighting for the FY 2016 Hospital VBP Program 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, since 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.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we finalized our proposal for a higher minimum number of cases for the three 30-day mortality measures for the FY 2015 Hospital VBP Program than was finalized for the FY 2014 Hospital VBP Program. We made this change in our policy in order to improve these measures' reliability given the relatively short performance period for these measures. However, we were concerned that the relatively higher minimum number of cases could result in a substantially larger number of hospitals being excluded from the Hospital VBP Program. We believe that we should make a concerted effort to include as many hospitals as possible in the program in order to offer quality incentives and encourage quality improvement.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53606 through 53607), we finalized our proposal that, for the FY 2015 Hospital VBP Program

and subsequent years, hospitals with sufficient data to receive at least two domain scores (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. We are proposing to continue this approach for the FY 2016 Hospital VBP Program and subsequent fiscal years for purposes of eligibility for the program. However, as detailed further below, we are proposing to reclassify the Hospital VBP Program's quality measurement domains beginning with the FY 2017 program to align more closely with CMS' National Quality Strategy, and we are seeking public comments on how we should determine minimum numbers of cases and measures under that proposed policy.

d. Proposed Domain Reclassification and Domain Weighting for the FY 2017 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53593 through 53594), we outlined one possible set of measure classifications based on the National Quality Strategy. However, we did not finalize our proposal to adopt quality measurement domains based on the National Quality Strategy for the FY 2016 Hospital VBP Program, because we understood stakeholders to be concerned about our proposal to reshape the Program's scoring methodology before hospitals had actual experience with the program and its value-based incentive payments.

However, we now believe that hospitals have accumulated practical experience with all components of the Hospital VBP Program, including performance periods and payment periods. As a result of our extensive outreach efforts to hospitals and stakeholders, as well as the practical experience with the first year of the program, we also believe that hospitals and other stakeholders generally understand the program's operations and scoring methodology. Therefore, we believe that we have addressed commenters' concerns, summarized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53594), that we should wait until hospitals have experienced the program fully before fundamentally reshaping its structure.

We are attempting to align all of our quality improvement efforts with the NQS, particularly because it is a patient-centered approach that aligns public and private efforts. We are aware that NQF uses NQS-based domains, and we also use those domains in development of other agency-specific efforts. We note further that stakeholders frequently request that HHS align its quality improvement efforts so that providers are not subjected to different measurement approaches, and we believe that adapting the Hospital VBP Program domain structure is one approach to achieving that goal. We believe that the longer we wait to adapt the Hospital VBP Program to the NQS domains, the more difficult it will be, and we believe we need a common framework as we begin alignment efforts between the Hospital IQR Program, the Hospital VBP Program, and the EHR Incentive Program. CMS's quality measurement strategic plan also centers on the NQS, and we believe that using these domains rewards hospitals for providing more efficient and more patient-centered care. The most recent Annual Progress Report to Congress addressing the NQS can be found on the Web site at: *http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf.*

Therefore, we are proposing to align the Hospital VBP Program's quality measurement domains with the NQS' quality priorities, with certain modifications discussed further below. We are proposing to adopt this realignment beginning with the FY 2017 Hospital VBP Program.

We are proposing to combine the priorities of Care Coordination and Patient and Caregiver Centered Experience of Care into one domain for purposes of aligning the Hospital VBP Program domains with the NQS priorities. Care Coordination aligns with the NQS priority stated as promoting effective communication and coordination of care. Patient and Caregiver Centered Experience of Care aligns with the NQS priority stated as ensuring that each person and family are engaged as partners in their care. We believe that, in order to be engaged as partners, effective communication and coordination of care must coexist. This notion is further exemplified by one of the 10 principles of the NQS, found at *http://www.ahrq.gov/workingforquality/nqs/principles.html,* which notes that ''Person-centeredness and family engagement, including understanding and valuing patient preferences, will guide all strategies, goals, and health care improvement efforts. The most successful health care experiences are often those in which clinicians, patients, and their families work together to make decisions.'' We believe that care coordination includes this shared decision-making among clinicians, patients, and their families, and further believe that a component of these important concepts can be captured with the HCAHPS measure.

Therefore, we believe that placing the HCAHPS measure into the proposed combined domain below will continue to encourage hospitals to focus on improving the patient's experience during acute care hospitalizations and will enable us to continue providing incentives that focus on patient and caregiver experience and coordination of care. However, with the exception of the HCAHPS measure described above, we do not believe that any of the other proposed measures for the FY 2016 Hospital VBP Program, which would form the basis for the FY 2017 program's measure set, should be placed into the proposed combined Patient and Caregiver Experience of Care/Care Coordination domain. We intend to consider proposing to adopt measures of care coordination in the future as they become available.

We may propose further refinements to the Hospital VBP Program domain structure in future years to accommodate the NQS' population health priority or other quality improvement priorities as appropriate, but will not propose to adopt a Population Health domain at this time.

We note that the proposed NQS-based domain structure combines measures of clinical processes and outcomes under the ''Clinical Care'' priority. In order to ensure that outcomes remain a principal focus of hospitals' quality improvement efforts, as well as to continue our effort to shift the program over time to include more measures of outcomes and efficiency, we are proposing to stratify the NQS-based Clinical Care domain into ''Clinical Care—Outcomes'' and ''Clinical Care—Process,'' which enables us to provide significant weight to measures of outcomes and avoid diluting hospitals' focus on measures of outcomes.

We note further that the proposed NQS-based domains include ''Efficiency and Cost Reduction,'' a domain priority that we believe is analogous to the current ''Efficiency'' domain finalized for the Hospital VBP Program, and a ''Safety'' domain. We have placed measures of outcomes into both the Clinical Care—Outcome and Safety

domains below and have generally distinguished between the two by focusing on the measures' direct impact on patients. The measures we are proposing to place into the Safety domain include measures of healthcare-associated infections and the AHRQ patient safety composite. We believe that hospitals must continue to focus quality improvement efforts on these outcome safety measures, which track infection and safety events that pose direct harm to patients.

Finally, as we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below. We believe that the proposed domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient and care giver experience.

We note further that the proposed domain weighting below places significant weight on measures of clinical outcomes, efficiency, and the patient experience, while also prioritizing safety and clinical processes. We believe that the proposed domain weighting appropriately balances the clinical quality priorities described by the NQS.

Therefore, we are proposing to adopt the following domains and domain weights for the FY 2017 Hospital VBP Program:

PROPOSED DOMAINS AND DOMAIN WEIGHTS FOR THE FY 2017 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL PROPOSED DOMAINS

Domain	Weight
Safety	15 percent.
Clinical Care	35 percent.
• Clinical Care—Outcomes.	• 25 percent.
• Clinical Care—Process.	• 10 percent.
Efficiency and Cost Reduction.	25 percent.
Patient and Caregiver Centered Experience of Care/Care Coordination.	25 percent.

While we believe there are advantages to aligning the Hospital VBP Program domains with the NQS domains, we also recognize that there may be advantages associated with maintaining consistency with previous years' domains. Accordingly, as an alternative to realigning the Hospital VBP Program's domain structure more closely with the NQS beginning with FY 2017, we also are inviting public comments on whether we should adopt the following domains and domain weighting, which would be consistent with the proposals outlined for FY 2016 above:

ALTERNATIVE DOMAIN WEIGHTS FOR THE FY 2017 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL PROPOSED DOMAINS

Domain	Weight
Clinical Process of Care	10 percent.
Patient Experience of Care	25 percent.
Outcome	40 percent.
Efficiency	25 percent.

We also seek public comments on how we should assign proposed measures to the new NQS-aligned domains, if finalized for FY 2017, and are seeking public comments on the following domain assignments for proposed FY 2016 measures, which would form the initial basis for the FY 2017 program's measure set:

Measure ID	Current domain	NQS-based domain
AMI–7a	Clinical Process of Care	Clinical Care—Process.
IMM–2	Clinical Process of Care	Clinical Care—Process.
PN–6	Clinical Process of Care	Clinical Care—Process.
SCIP–Inf–1	Clinical Process of Care	Clinical Care—Process.
SCIP–Inf–2	Clinical Process of Care	Clinical Care—Process.
SCIP–Inf–3	Clinical Process of Care	Clinical Care—Process.
SCIP–Inf–4	Clinical Process of Care	Clinical Care—Process.
SCIP–Inf–9	Clinical Process of Care	Clinical Care—Process.
SCIP–Card–2	Clinical Process of Care	Clinical Care—Process.
SCIP–VTE–2	Clinical Process of Care	Clinical Care—Process.
HCAHPS	Patient Experience of Care	Patient and Caregiver Centered Experience of Care/Care Coordination.
CAUTI	Outcome	Safety.
CLABSI	Outcome	Safety.
MORT–30–AMI	Outcome	Clinical Care—Outcomes.
MORT–30–HF	Outcome	Clinical Care—Outcomes.
MORT–30–PN	Outcome	Clinical Care—Outcomes.
PSI–90	Outcome	Safety.
SSI	Outcome	Safety.
MSPB–1	Efficiency	Efficiency and Cost Reduction.

We also seek comment on how we should address minimum numbers of cases and measures under sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act if we finalize this domain structure for the FY 2017 program. If we adopted the NQS-based domains solely for purposes of constructing the TPS, we could retain the general case and measure minimums structure adopted for prior program years. However, given the requirement in section 1886(o)(1)(C)(iii) of the Act that the Secretary conduct an independent analysis of what numbers are appropriate, we are also considering if we should commission such an analysis for the NQS domains, as modified. We are seeking public comments on this issue.

e. Proposed Disaster/Extraordinary Circumstance Waivers Under the Hospital VBP Program

We are concerned that hospital performance under the Hospital VBP Program might be adversely impacted as a direct result of a significant natural disaster or other extraordinary circumstance. We are aware, for example, that Hurricane Sandy forced

some hospitals in the New York-New Jersey-Connecticut area to close during the autumn of 2012, which impacted their ability to report quality measure data that will be used for both the FY 2014 and FY 2015 Hospital VBP Programs. We also recognize that hospitals that are closed during a portion of a performance period may still be eligible to receive a TPS and value-based incentive payments based on their measured quality performance during the remaining portion of the performance period for a fiscal year.

However, we also are aware that many hospitals that were affected by Hurricane Sandy nevertheless remained open both during and after the storm, and we are concerned more generally that these hospitals, as well as other hospitals that are able to remain open despite being impacted by a local disaster or other extraordinary circumstance, might experience a decline in performance as a direct result of remaining open. For example, a hospital might be able to demonstrate that its performance on the HCAHPS survey was adversely impacted as a direct result of remaining open during or after a natural disaster if the hospital became overcrowded due to a neighboring hospital's closure, or understaffed due to the inability of staff to get to work. We believe that these types of unforeseen extraordinary circumstances could substantially affect the ability of the hospital to perform at the same level at which it might otherwise have performed if the natural disaster or extraordinary circumstance had not occurred, and we are concerned that using cases and claims from this period to generate the TPS might negatively, and unfairly, impact the value-based incentive payment amount that the hospital would otherwise receive.

Currently, hospitals participating in the Hospital IQR Program may request that we grant an extension or waiver of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. However, we do not believe this process is entirely sufficient for the Hospital VBP Program. The Hospital IQR Program's extraordinary circumstances extensions/waiver process allows hospitals that have been granted an extension/waiver to receive the full annual percentage increase under the IPPS for the applicable fiscal year even though they did not submit data on measures in the same time, form, and manner required of other hospitals. To the extent that a hospital, as a result of receiving an extension or waiver under the Hospital IQR Program, does not report the minimum number of cases or measures under the Hospital VBP Program (as determined appropriate by the Secretary under sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act), that hospital will be excluded from the Hospital VBP Program for the applicable fiscal year.

However, the Hospital IQR Program extraordinary circumstance extension/waiver process does not address the situation we are concerned with here; namely, where a hospital is able to continue to report data on measures that are included in both the Hospital IQR Program and the Hospital VBP Program, but can demonstrate that its Hospital VBP measure rates are negatively impacted as a result of a natural disaster or other extraordinary circumstance and, as a result, the hospital receives a lower value-based incentive payment. Therefore, we are proposing to adopt a Hospital VBP Program extraordinary circumstance waiver process.

In developing our proposed approach, we considered the feasibility of adopting a waiver that would allow a hospital to not have the measure data submitted during the affected time period included in its measure scores. This type of waiver policy would enable affected hospitals to continue to participate in the Hospital VBP Program for a given fiscal year if they continued to meet applicable measure and case minimums despite the fact that their TPS would not include data that is the subject of the waiver. Therefore, this policy could prevent the possibility that a hospital's TPS is significantly, and negatively, affected by a natural disaster or other extraordinary circumstance, which we believe would alleviate our concerns.

However, implementing this type of data waiver presents certain operational difficulties. While chart-abstracted measures generally are reported using a date of service that would enable us to correctly identify which data should be excluded, the same is not necessarily true of patient experience of care measure data because HCAHPS survey dates do not align with service dates; instead, they are dependent on the timing of the survey's completion after discharge.

A further complication arises with certain claims-based measures. For example, the risk adjustment methodology currently in use for the 30-day mortality measures requires a fixed dataset for computation of all hospitals' risk-adjusted measure rates. Adding or removing data from the national claims set used to calculate a mortality measure's rates for a given time period therefore requires recalculation of all hospitals' measure rates, as the risk profile used to adjust hospitals' measured performance for the time period would have changed. In addition, in light of our policy to generate a TPS for hospitals that receive scores on fewer than all domains, we are concerned that proposing to adopt an extraordinary circumstances ''waiver'' process that would apply only to the clinical process of care domain data that we may relatively easily remove from scoring would be ineffective. We do not believe that waiving only clinical process of care domain data would mitigate the effects of a disaster or other extraordinary circumstances on hospitals' TPSs under the program, particularly if hospitals' performance on all measures is affected significantly by those circumstances. An increase in measured mortality rates, for example, would not be mitigated by a clinical process of care-centered waiver, and could penalize the hospital.

Given the operational constraints discussed above, we believe that the best way to implement an extraordinary circumstances waiver under the Hospital VBP Program is to interpret the minimum numbers of cases and measures requirement in section 1886(o)(1)(C)(ii)(III) and (IV) of the Act to enable us to ''waive'' all applicable quality measure data from a performance period and, thus, exclude the hospital from the Hospital VBP Program for a fiscal year during which the hospital has experienced a disaster or other extraordinary circumstance.

Under this policy, a hospital struck by a natural disaster or other extraordinary circumstance would be able to request a Hospital VBP Program disaster/extraordinary circumstance waiver at the same time that it requests an extraordinary circumstance waiver under the Hospital IQR Program. The hospital would submit the Hospital IQR Program extension/waiver request form, including any available evidence of the impact of the extraordinary circumstances on the hospital's quality measure performance, and would note that it also seeks a waiver from the Hospital VBP Program for the program year in which the same data could be used as performance period data to generate a TPS based on the measures included in the Hospital VBP Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51652), we finalized a requirement that affected hospitals submit their requests within 30 days of the date that the extraordinary circumstance occurred. We believe that this timeframe is appropriate for our proposed waiver process for the Hospital VBP Program as it aligns with

the current requirements under the Hospital IQR Program and forestalls the possibility of hospitals attempting to ''game'' their Hospital VBP Program scores by requesting a waiver after they receive their Percentage Payment Summary Reports for a given fiscal year.

We will review waiver requests and, at our discretion based on our evaluation of the impact of the disaster/extraordinary circumstances on the hospital's quality measure performance, provide a response to the hospital. We intend to notify hospitals about our Hospital VBP Program waiver decisions concurrent with decisions made under the Hospital IQR Program's waiver process.

For these reasons, we are proposing that the phrases ''minimum number of measures that apply to the hospital'' in section 1886(o)(1)(C)(iii) of the Act and ''minimum number of cases for the measures that apply to the hospital'' in section 1886(o)(1)(C)(iv) of the Act do not include any measures or cases that a hospital has submitted during a performance period for which it is granted a Hospital VBP Program disaster/extraordinary circumstance waiver.

We intend to implement this policy in a limited fashion, and based on prior experience with the Hospital IQR Program, anticipate providing such waivers only to a small number of hospitals. We do not intend to allow hospitals to use this proposed process to seek exclusion from the Hospital VBP Program solely because of comparatively poor performance under the Program's scoring methodology; rather, we intend only to provide relief to hospitals whose performance suffered as a result of a disaster or other extraordinary circumstances.

We are inviting public comments on this proposal. We are specifically interested in public comments on the structure of the proposed process, and if we should consider implementing the process differently.

10. Applicability of the Hospital VBP Program to Hospitals

a. Background

Section 1886(o)(1)(C) of the Act specifies how the Hospital VBP Program applies to hospitals. Specifically, the term ''hospital'' is defined under section 1886(o)(1)(C)(i) of the Act as a ''subsection (d) hospital (as defined in section 1886(d)(1)(B [of the Act])).'' Section 1886(o)(1)(C)(ii) of the Act sets forth a list of exclusions to the definition of the term ''hospital'' with respect to a fiscal year, including a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program), a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients, a hospital for which there are not a minimum number of measures that apply to the hospital for the applicable performance period for the fiscal year, and a hospital for which there are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In addition, section 1886(o)(1)(C)(iv) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, the Secretary may exempt the hospital from the Hospital VBP Program if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. We interpret the reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

b. Proposed Minimum Numbers of Cases and Measures for the FY 2016 Hospital VBP Program Outcome Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we finalized minimum numbers of cases and measures for the FY 2015 Hospital VBP Program's Outcome domain. For the finalized 30-day mortality measures, we finalized a 25-case minimum for FY 2015. For the AHRQ PSI composite measure, we adopted AHRQ's methodology, which provides a score on the measure to any hospital with at least three cases on any underlying indicator. For the CLABSI measure, we adopted CDC's minimum case criteria, which calculates a standardized infection ratio for a hospital on the CLABSI measure if the hospital has 1 predicted infection during the applicable period. We also finalized our policy to provide a TPS to hospitals with sufficient cases in at least two of the four finalized quality measure domains (77 FR 53607).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74534) we concluded, based on an independent analysis, that the minimum number of measures that a hospital must report in order to receive a score on the Outcome domain is two measures. We continue to believe that this minimum number is appropriate for the expanded Outcome domain because adding measure scores beyond the minimum number of measures has the effect of enhancing the domain score's reliability. We therefore are proposing to retain the finalized minimum number of measures for the Outcome domain for the FY 2016 Hospital VBP Program.

We are inviting public comment on these proposals.

c. Hospitals Paid Under Section 1814(b)(3) of the Act

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53607 through 53608), beginning with the FY 2014 Hospital VBP Program, we adopted a new procedure for submission of the report in order for a Maryland hospital to be exempt from the Hospital VBP Program for a fiscal year. Under this finalized procedure, if the State seeks an exemption with respect to a particular program year, it would need to submit a report that meets the requirements of section 1886(o)(1)(C)(iv) of the Act in a timeframe that allows it to be received by the Secretary on or before November 15 prior to the effective fiscal year (for example, the report seeking an exemption from the FY 2014 Hospital VBP Program would have to be received by the Secretary no later than November 15, 2012). We stated that we anticipate notifying the State, as well as each hospital for which the State has requested an exemption, of our decision whether to grant the request no later than 90 days following the exemption request deadline.

We received an FY 2014 exemption request from the Maryland Health Services Cost Review Commission and the State of Maryland Department of Health and Mental Hygiene in November 2012, and the Secretary approved the exemption request on December 19, 2012.

We determined that Maryland meets or exceeds the patient health outcomes and cost savings requirements for exemption from the FY 2014 Hospital VBP Program. In terms of patient health outcomes, the Maryland Quality Based Reimbursement (MQBR) program focuses rewarding high quality care on hospital performance in similar clinical areas as the Hospital VBP Program (heart attack, heart failure, pneumonia, surgical processes of care and infection control). In general, the relevant health outcomes for the State's hospitals cited in its request achieve or surpass the current national results for comparable quality process and closely related clinical outcomes. In terms of cost savings, both the Hospital VBP Program

and the MQBR reward high performers in a revenue-neutral manner. In this way, Maryland has achieved cost savings under its quality programs that meet any documented savings under the Hospital VBP Program, thereby meeting the standard specified in section 1886(o)(1)(C)(iv) of the Act for hospitals paid under section 1814(b)(3) of the Act.

I. Proposed Implementation of Hospital-Acquired Condition (HAC) Reduction Program for FY 2015

1. Background

a. Overview

CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries. Accordingly, as part of that effort, we have, in recent years, undertaken a number of initiatives to reduce the number of hospital-acquired conditions (HACs) among Medicare beneficiaries. HACs are conditions that patients acquire while receiving treatment for another condition in an acute care health setting. HACs include hospital-acquired infections (HAIs), such as surgical site infections, as well as conditions such as foreign objects retained after surgery. HACs constitute an adverse event for the patient and a financial burden on the health care system. Most HACs, especially those stemming from medical errors, represent a leading cause of mortality in the United States.[48] Deaths from HAIs alone are twice as high as those from HIV/AIDS and breast cancer combined.[49] Many common HACs can be prevented through the proper application of evidence-based guidelines. Yet, surveys reveal that 87 percent of hospitals do not follow such guidelines.[50] Further, HACs constitute a significant economic burden on the health care system. For example, in 2009, the CDC estimated that preventable HAIs alone added nearly $6 billion to U.S. health care costs each year.[51] Accordingly, we believe that our continued efforts to reduce HACs are vital to improving patients' quality of care, and reducing complications and mortality, while simultaneously decreasing costs.

In section II.F. of the preamble of this proposed rule, we discuss prior and ongoing rulemakings to implement the provisions of section 5001(c) of the Deficit Reduction Act (DRA) of 2005. Section 5001(c) of the DRA requires the Secretary to identify conditions by October 1, 2007 that: (a) Are high cost or high volume or both; (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence based guidelines. An adjustment to the MS–DRG payment under the IPPS is made for identified HACs. This regulatory action has supported our efforts to encourage hospitals to reduce HACs.

Our initiatives to reduce HACs continued in 2009, when we developed National Coverage Determinations (NCDs) for the Medicare Program to eliminate ''never events.'' These ''never events'' stemmed from a 2002 report conducted by the NQF that listed 27 adverse events, defined as serious reportable events, that were both serious and largely preventable.[52] Under these NCDs, we have specified that Medicare does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs: (1) A different procedure altogether; (2) the correct procedure but on the wrong body part; or (3) the correct procedure but on the wrong patient.[53]

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50196), we adopted 8 HAC measures into the Hospital IQR Program for the FY 2012 payment determination. These quality measures comprise additional efforts to promote quality of care by reducing the number of HACs in an acute care setting. We have been publicly reporting on these eight HAC measures successfully on the *Hospital Compare* Web site since September 2010.

As described above, the reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and costs of care. In accordance with section 1886(p) of the Act, the HAC Reduction Program aligns with our national strategy to improve health care quality by promoting the prevention of HACs, such as ''serious reportable events'' and HAIs. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur through implementing the adjustments required by section 1886(p) of the Act. We believe our efforts in using payment adjustments and our measurement authority will encourage hospitals to eliminate the incidence of HACs that could be reasonably prevented by applying evidence-based guidelines.

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 applicable hospitals to reduce 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 programs 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. 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. 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.

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

[48] Kohn L T, Corrigan J M., Donaldson MS (Institute of Medicine) To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press, 2000.

[49] Binder, Leah F. The Leapfrog Group Testimony before the House of Representatives Committee of Oversight and Government Reform, April 16, 2008. Available at: *http://www.leapfroggroup.org/policy_leadership/leapfrog_news/4732651*.

[50] Id.

[51] Centers for Disease Control, The Direct Medical Costs of Healthcare Associated Infections in US Hospitals and the Benefits of Prevention March, 2009. Available at: *http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf*.

[52] National Quality Forum (NQF), *Serious Reportable Events in Healthcare—2011 Update: A Consensus Report,* Washington DC: NQF (2011).

[53] Center for Medicare and Medicaid Services (CMS), National Coverage Determination (NCD) for, *Surgical or Other Invasive Procedure Performed on the Wrong Body Part* (140.7), Pub–100–3 (2009); *Surgical or Other Invasive Procedure Performed on the Wrong Patient* (140.8), Pub 100–3 (2009); *Wrong Surgery Performed on a Patient* (140.9), Pub 100–3 (2009).

provides the delivery of confidential reports to applicable hospitals with respect to HACs of the applicable hospital during the applicable period. 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, and submit corrections for, the information to be made public with respect to the HACs 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 information be posted on the *Hospital Compare* Web site on the Internet 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 an applicable period, the provision of confidential reports submitted to the applicable hospital, and the information publically reported on the *Hospital Compare* Web site.

3. Proposals To Implement the HAC Reduction Program

In this proposed rule, we are proposing the general framework for implementation of the HAC Reduction Program for the FY 2015 implementation. We are including the following proposals for the program: (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.

In this proposed rule, we are proposing to establish the rules governing the payment adjustment under the HAC Reduction Program at Subpart I of 42 CFR part 412 (proposed §§ 412.170 and 412.172). We also are proposing to amend existing § 412.150 (the section that describes the basis and scope of Subpart I of Part 412, which contains the regulations governing adjustments to the base operating DRG payment amounts under the IPPS for inpatient operating costs) to incorporate the basis and scope of proposed §§ 412.170 and 412.172 for the HAC Reduction Program. We discuss each of the proposed regulatory provisions under the appropriate subject area below.

a. Proposed Definitions

In accordance with the provisions of section 1886(p) of the Act, we are proposing to include, under proposed § 412.170, definitions for the terms ''hospital-acquired condition,'' ''applicable hospital,'' and ''applicable time period.''

• Hospital-acquired condition. In accordance with the definition of ''hospital-acquired condition'' in section 1886(p)(3) of the act, we would include a definition of the term in the regulations to read: ''*Hospital-acquired condition* is a condition as described in section 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.''

We also refer readers to section II.F. of the preamble of this proposed rule where we discuss the HACs that have been identified and selected by the Secretary through FY 2013 in accordance with the provisions of section 1886(d)(4)(D)(iv) of the Act as established by section 5001(c) of the DRA of 2005.

• Applicable Hospital. Section 1886(p)(2)(A) of the Act specifies that, for the purpose of the HAC Reduction program, an ''applicable hospital'' is a subsection (d) hospital that meets certain criteria. A subsection (d) hospital is defined in section 1886(d)(1)(B) of the Act, in part, as a ''hospital located in one of the fifty States or the District of Columbia'', subject to certain exceptions. We also note that, for purposes of determining applicable hospitals under the HAC Reduction Program, subsection (d) hospitals include hospitals paid under a waiver under section 1814(b)(3) of the Act (that is, Maryland hospitals). Section 1886(p)(2)(B) of the Act specifies that ''with respect to a subsection (d) hospital, [a hospital is considered to be an applicable hospital if] . . . the subsection (d) hospital is in the top quartile of all subsection (d) hospitals, relative to the national average, of hospital acquired conditions during the applicable period, as determined by the Secretary.'' Therefore, we are proposing to define an ''applicable hospital'' as ''a hospital described in section 1886(d)(1)(B) of the Act (including a hospital in Maryland that is paid under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the hospital inpatient prospective payment system) so long as the hospital meets the criteria specified under § 412.172(e).''

We note that while all subsection (d) hospitals, including hospitals paid under section 1814(b)(3) of the Act, would be used to determine which hospitals are ''applicable hospitals,'' as required by section 1886(p)(2)(B) of the Act, we have identified several types of hospitals where subsection (d) status may not be clear for purposes of determining which hospitals are or are not subject to the provisions of the HAC Reduction Program. A subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs. Therefore, hospitals and hospital units that are excluded from the IPPS would not be considered when determining ''applicable hospitals'' nor would they be determined to be ''applicable hospitals'' subject to the payment adjustment under the HAC Reduction Program. Similarly, CAHs would not be considered when determining ''applicable hospitals,'' nor would they be determined to be ''applicable hospitals'' subject to the payment adjustment under the HAC Reduction Program, because they do not meet the definition of a ''subsection (d) hospital.'' CAHs are separately defined under section 1886(mm) of the Act and are paid under a reasonable cost methodology under section 1814(l) of the Act. An Indian Health Services hospital enrolled as a Medicare provider meets the definition of a subsection (d) hospital and, therefore, would be considered in determining ''applicable hospitals'' and would be considered to be an ''applicable hospital'' under the HAC Reduction Program. In addition, hospitals that are SCHs, although they may be paid under a hospital-specific rate instead of the Federal rate under the IPPS, are subsection (d) hospitals and, therefore, would be included in determining ''applicable hospitals'' and would be considered to be an applicable hospital under the HAC Reduction Program. Hospitals located in the Territories, including Puerto Rico, are not subsection (d) hospitals. Section 1886(d)(9)(A) of the Act separately defines a ''subsection (d) Puerto Rico hospital'' as a hospital that is located in Puerto Rico and that ''would be a subsection (d) hospital . . . if it were located in one of the 50 States.'' However, because they are not located

in ''one of the fifty States,'' Puerto Rico hospitals are not subsection (d) hospitals and, therefore, would not be included in determining ''applicable hospitals,'' nor would they be considered to be an ''applicable hospital'' under the HAC Reduction Program. Finally, hospitals paid under the authority of section 1814(b)(3) of the Act are located in Maryland, which is ''one of the fifty States'' as described under section 1886(d)(1)(B) of the Act. Therefore, these Maryland hospitals are subsection (d) hospitals and would be included in determining ''applicable hospitals'' and, unless the Secretary exempts them from the application of the payment adjustment under the HAC Reduction Program under the authority of section 1886(p)(2)(C) of the Act, would be considered to be ''applicable hospitals'' under the HAC Reduction Program.

We are inviting public comments on whether clarification is required for additional types of hospitals.

• Applicable Time Period. In accordance with the proposal and discussion in section V.I.3.d. of this preamble regarding the proposed performance scoring methodology for proposed measures for selected conditions and a risk-adjustment methodology under the HAC Reduction Program, we are proposing to define the ''applicable period'' as, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the Total HAC Score for the Hospital-Acquired Reduction Program

We are inviting public comments on these proposed definitions.

b. Proposed Payment Adjustment Under the HAC Reduction Program, Including Exemptions

(1) Basic Payment Adjustment

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 discharges beginning on October 1, 2014. Section 1886(p)(1) of the Act specifies that 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. As specified in the statute, this payment adjustment is calculated and made after payment adjustments under sections 1886(o) and 1886(q) of the Act, the Hospital VBP Program and the Hospital Readmissions Reduction Program respectively, are calculated and made. (We note that the Hospital VBP Program is discussed in section V.H. of the preamble of this proposed rule and the Hospital Readmissions Reduction Program is discussed in section V.G. of the preamble of this proposed rule.) 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. Therefore, we are proposing to specify in proposed § 412.172(b) that, ''For applicable hospitals, beginning with discharges occurring during FY 2015, the amount of payment under this section [proposed § 412.172], or section 1814(b)(3) of the Act, as applicable, for such discharges shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under this section [proposed § 412.172], or section 1814(b)(3) of the Act. This amount of payment will be determined after the application of the payment adjustment under the Hospital Readmissions Reduction Program under § 412.154, and the adjustment made under the Hospital Value-Based Purchasing Program under § 412.162, and section 1814(l)(4) but without regard to this section 1886(p) of the Act).''

We are inviting public comments on this proposal.

(2) Applicability to Maryland Hospitals

Section 1886(p)(2)(c) of the Act specifies that the Secretary may exempt hospitals paid under 1814(b)(3) ''from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the state for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.'' Accordingly, a program established by the State of Maryland that could serve to exempt hospitals in the State from the HAC Reduction Program would focus on hospitals operating under the waiver provided by section 1814(b)(3) of the Act, that is, those hospitals that would otherwise have been paid by Medicare under the IPPS, absent this provision. As we describe in section V.I.3. of the preamble of this proposed rule, because hospitals paid under section 1814(b)(3) of the Act are subsection (d) hospitals, they would be included in determining ''applicable hospitals'' (subject to the payment adjustment under the HAC Reduction Program), and unless the Secretary exempts these hospitals from the application of payment adjustments under the HAC Reduction Program under the authority of section 1886(p)(2)(C) of the Act, they are considered to be ''applicable hospitals'' (subject to the payment adjustments in the HAC Reduction Program) under the HAC Reduction Program.

In this proposed rule, we are proposing to establish criteria for evaluation to determine whether Maryland should be exempted from the application of the payment adjustments under the HAC Reduction Program for a given fiscal year. Under proposed § 412.172(c), we would specify that ''CMS will determine whether to exempt Maryland hospitals that are paid under section 1814(b)(3) of the Act and not under the hospital inpatient prospective payment system. . . .'' and that, absent the provisions of section 1814(b)(3) of the Act, would be paid under section 1886(d) of the Act from the application of payment adjustments under the Hospital-Acquired Condition Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital acquired conditions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings for the Hospital-Acquired Condition Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act. We would specify in the proposed regulations that ''CMS will establish criteria for evaluation of Maryland's annual report to the Secretary to determine whether Maryland will be exempted from the application of payment adjustments under this program for a given fiscal year.'' We would also specify that ''Maryland's annual report to the Secretary and request for exemption from the Hospital-Acquired Condition Reduction Program must be resubmitted and reconsidered annually.'' We are proposing that, for FY 2015, Maryland would submit a preliminary report to us by January 15, 2014 and a final report to us by June 1, 2014.

We note that our proposed criteria to evaluate Maryland's program is for FY 2015, the first year of the payment adjustment under the HAC Reduction Program, and that our evaluation criteria may change through notice and comment rulemaking as this program evolves.

We are inviting public comments on our proposals.

c. Proposed Measure Selection and Conditions, Including a Proposed Risk-Adjustment and Scoring Methodology

(1) General Selection of Proposed Measures

We are proposing measures and a scoring methodology for the HAC Reduction Program in this FY 2014 proposed rule. Although we are not required under section 1886(p) of the Act to address specific measure scoring methodologies regarding the HAC Reduction Program in notice-and-comment rulemaking, as required under the Hospital VBP Program, we believe that it is important to set forth such scoring methodologies for each individual HAC measure, in order for the public to understand how the measures discussed and finalized in this year's rulemaking relate to the performance methodology used to determine the applicable hospitals subject to the payment adjustment under the HAC Reduction Program.

(2) Measure Selection and Scoring Methodology

As described more fully below, we are proposing initially to adopt eight measures for the FY 2015 determination under the HAC Reduction Program. Several of these measures are already part of the Hospital IQR Program and are reported on the *Hospital Compare* Web site. We note that all eight measures proposed for the HAC Reduction Program follow the criteria established by the DRA of 2005 in that they consist of high-volume or high-cost conditions that could be prevented by the use of evidence-based guidelines (we refer readers to section II.F. of the preamble of this proposed rule for further information).

In this proposed rule, we are proposing the measure selection and methodology used to determine the Total HAC Score. For measure selection under the HAC Reduction Program, we are proposing to group the measures into separate domains (Domain 1 and Domain 2) to calculate a Total HAC Score in order to determine the payment adjustment. For Domain 1, we are discussing two alternatives, and seeking to finalize a policy based upon public comment received regarding these alternatives. The first approach represents our proposal, as it is our preferred choice. However, we are including an alternative approach for public comment. Both approaches would utilize AHRQ Patient Safety Indicators (PSIs) and CDC Healthcare Associated Infection (HAI) measures collected via the National Healthcare Safety Network (NHSN), and both approaches would be grouped into two separate domains. Domain 1 would include the AHRQ PSI measures. Domain 2 would include CDC HAI measures. As explained below, these two domains would be used as part of calculating the Total HAC Score, which is the score used to determine the top quartile of subsection (d) hospitals subject to the payment adjustment under the HAC Reduction Program. The difference between our proposal and the alternative approach, as illustrated by Table A below, lies in the AHRQ measures proposed to be used in Domain 1. Domain 2 would be the same under either approach.

We are proposing to group the AHRQ and CDC HAI measures into separate domains to calculate a Total HAC Score because of the several major differences between the AHRQ and the CDC HAI measures. First, the AHRQ and CDC HAI measures use different data sources for their respective calculations. The AHRQ measures use Medicare FFS claims data and the CDC HAI measures use chart-abstracted data. Second, the AHRQ measures capture occurrences of adverse events among Medicare FFS discharges, while the CDC HAI measures capture adverse events to Medicare and non-Medicare patients alike. Third, the AHRQ measure results [54] are risk-adjusted and reliability-adjusted based on a 24-month data period, whereas the CDC HAI measures are a Standardized Infection Ratio (SIR) based on quarterly reporting. In addition, the AHRQ measures identify adverse events occurring across units within a facility, while the CDC HAI measures identify adverse events at the unit level. The SIR adjusts for differences in levels of infection risk in patients. The CDC SIR measures are calculated by dividing the total facility number of observed HAI events by the total facility number of predicted HAI events. The facility must have ≥1 predicted HAI event during the reporting time period, for example, calendar quarter, for the measure to be calculated. The number of predicted HAI events is first calculated for each patient care location by multiplying the location's denominator (that is, the number of device days, procedure days, or patient days, depending on the HAI) by the NHSN-specific HAI rates from a standard population during a baseline time period, and dividing by 1.000. Then the predicted number of specific HAIs are summed across locations and used as the total facility number of predicted HAI events to reduce the overall SIR for a facility. Currently, CAUTI and CLABSI are inclusive of patients in the intensive care unit only. However, in this proposed rule, we are seeking public comment on the expansion of the population to include medical wards, surgical wards, and medical/surgical wards. (We refer readers to section IX.A. of the preamble of this proposed rule for a discussion of the Hospital IQR Program.) Furthermore, the AHRQ measures are risk-adjusted at the patient level,[55] while the CDC HAI measures are risk-adjusted at the hospital-level and patient-care unit level. Specifically, the calculation of the AHRQ measures takes into consideration the risk factors of the patient's age, gender, and comorbidities, while CDC HAI measures account for risk factors, including patient location within the facility, medical school affiliation, and bed size of patient care unit. Because of the important differences mentioned above in the calculation of the two sets of measures, combining measure results into a single composite measure would decrease the reliability of the Total HAC Score model. As a result, we are proposing to group the AHRQ and the CDC HAI measures into two separate domains.

Both our proposal and the alternative approach under Domain 1 support the agency's efforts to identify and monitor adverse events and inform hospitals about their patient safety performance. Both approaches also will allow us to compare hospital performance and to distinguish better performing hospitals from poor performing hospitals. Thus, the measures under either Domain 1 approach would result in a consistent scoring.

However, our proposed approach for Domain 1 would provide simpler results to interpret, allow a hospital to use the results to target patient safety improvement efforts, and avoid overlap between the two measure domains. Therefore, we believe that our proposed approach for Domain 1 provides hospitals with the most comprehensive picture of patient safety performance and is the method we are proposing to use.

Under our proposed approach, we are proposing to use the following six AHRQ measures for Domain 1 (Table A):

- Pressure ulcer rate (PSI 3);
- Volume of foreign object left in the body (PSI 5);
- Iatrogenic Pneumothorax rate (PSI 6);

[54] With the exception of PSI 5 (Volume of foreign object left in body), which is not risk-adjusted or reliability-adjusted.

[55] The exception is PSI 5 (Volume of foreign object left in body), which is not risk-adjust or reliability-adjusted.

- Postoperative physiologic and metabolic derangement rate (PSI 10);
- Postoperative pulmonary embolism (PE) or deep vein thrombosis rate (DVT) (PSI 12); and
- Accidental puncture and laceration rate (PSI 15).

Under the alternative approach, the measures under Domain 1 would consist of a Complications/Patient Safety for Selected Conditions composite (PSI 90). This composite is made up of the following eight individual component PSIs:

- Pressure ulcer rate (PSI 3);
- Iatrogenic Pneumothorax rate (PSI 6);
- Central venous catheter-related blood stream infection rate (PSI 7);
- Postoperative hip fracture rate (PSI 8);
- Postoperative pulmonary embolism (PE) or deep vein thrombosis rate (DVT) (PSI 12);
- Postoperative sepsis rate (PSI 13);
- Wound dehiscence rate (PSI 14); and
- Accidental puncture and laceration rate (PSI 15).

For Domain 2, regardless of the approach used for Domain 1, we are proposing to use CDC HAI measures. For FY 2015, we are proposing to use the CLABSI and CAUTI measures. Both of these measures are currently part of the Hospital IQR Program, are NQF endorsed, are publicly reported on the *Hospital Compare* Web site and were recommended by the MAP for use in the HAC Reduction Program. For FY 2016, we are proposing to add Surgical Site Infection (SSI), which is stratified by two conditions: Colon surgery and abdominal hysterectomy. For 2017, we are proposing to add Methicillin-resistant Staphylococcus aurus (MRSA) Bacteremia and *Clostridium difficile* infection. These measures are also part of the Hospital IQR Program and are being proposed for the Hospital VBP Program.

Table A.--Proposed Measures for the Hospital-Acquired Condition Reduction Program

Domain 1: AHRQ Patient Safety Indicators	
Proposed Approach: 6 individual measures (FY 2015 onward)	**Alternative Approach: One composite of 8 component indicators (FY 2015 onward)**
PSI-3 (Pressure ulcer rate) **PSI-5** (Foreign object left in body) **PSI-6** (Iatrogenic pneumothorax rate) **PSI-10** (Postoperative physiologic and metabolic derangement rate) **PSI-12** (Postoperative PE/DVT rate) **PSI-15** (Accidental puncture & laceration rate)	**PSI-90** { PSI-3 (Pressure ulcer rate) PSI-6 (Iatrogenic pneumathorax rate) PSI-7 (Central venous catheter-related blood stream infections rate) PSI-8 (Postoperative hip fracture rate) } PSI-12 (Postoperative PE/DVT rate) PSI-13 (Postoperative sepsis rate) PSI-14 (Wound dehiscence rate) PSI-15 (Accidental puncture & laceration rate)

Domain 2: CDC HAI Measures Apply to Proposed Approach and Alternative Approach (Multiple FYs)
• Central Line-associated Blood Stream Infection (CLABSI) (FY 2015 onward) • Catheter-associated Urinary Tract Infection (CAUTI) (FY 2015 onward) • Surgical Site Infection (SSI): ◦ SSI Following Colon Surgery (FY 2016 onward) ◦ SSI Following Abdominal Hysterectomy (FY 2016 onward) • Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia (FY 2017 onward) • *Clostridium difficile* (FY 2017 onward)

We are inviting public comment on whether the proposed approach or the alternative approach would better serve the HAC Reduction Program.

(3) Applicable Time Period

We are proposing a 2-year applicable period to collect data that would be used to calculate the Total HAC Score. For Domain 1 (AHRQ measures), we are proposing a 2-year data period to calculate the measures based on recommendations from AHRQ, the measure developer. In addition, an analysis by Mathematica Policy Research, a CMS contractor,[56] shows that, with a 24-month data period, 50 to 90 percent of hospitals attain a moderate or high level of reliability for the proposed AHRQ measures. We believe that the proposed 24-month data period described below would provide hospitals and the general public the most current data available. The proposed 24-month data period also would allow time to complete the complex calculation process for these measures, to perform comprehensive quality assurance to enhance the accuracy of measure results, and to disseminate confidential reports on hospital-level results to individual hospitals.

For FY 2015, we are proposing to use the 24-month period from July 1, 2011 through June 30, 2013 as the applicable time period for the AHRQ measures. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculation of measure results for FY 2015. This includes claims data from the 2011, 2012, and 2013 Inpatient Standard Analytic Files (SAFs). The national and hospital-specific rates for PSI 6, PSI 12, and PSI 15 are available on the Hospital Compare Web site. The hospital level PSI–90 composite bucket also is available on the *Hospital Compare* Web site.[57]

The CDC measures are currently collected and calculated on a quarterly basis. However, for purposes of the HAC Reduction Program, we are proposing to use 2 years of data to calculate the Domain 2 score so Domain 1 and Domain 2 are calculated using 24 months of data. For FY 2015, we are proposing to use calendar years 2012 and 2013 for the HAC Reduction Program.

(4) Measure Calculations

The AHRQ PSI measures are calculated using ICD–9–CM diagnosis and/or procedure codes and, for the secondary diagnoses, the present on admission (POA) value associated with each secondary diagnosis in the claim. POA data indicate whether an adverse event occurred during the hospital stay, or was already present at the time of admission. AHRQ measures also reflect the quality of inpatient care based on patient safety events that occurred during hospital stays. The FY 2008 IPPS final rule requires that all hospitals paid under the IPPS report on whether a diagnosis is present on admission (72 FR 47201). We note that in section II.F. of the preamble of this proposed rule, we also are proposing to extend this requirement to subsection (d) Maryland hospitals paid under the waiver at section 1814(b)(3) of the Act. The specifications of PSIs 3, 5, 6, 10, 12, 15, and the individual components for the composite PSI 90 can be found on the Web site at: *http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx*. For the composite PSI 90, the calculation, the individual component weighting scheme and the risk-adjustment methodology can be found on the Web site at: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V44/Composite_User_Technical_Specification_PSI%20V4.4.pdf*. A detailed discussion of the measure specifications and methodology of the AHRQ Patient Safety Indicators (PSIs) can be found on the Web site at: *http://www.qualityindicators.ahrq.gov/modules/psi_resources.aspx*.

For the HAC Reduction Program, we are proposing that the same rules used for the Hospital IQR Program be applied to determine whether the AHRQ individual rate-based measures in our proposed approach to Domain 1, including PSI 3, PSI 5, PSI 6, PSI 10, PSI 12, and PSI 15, are calculated for a hospital. In particular, under this proposal, for each of these measures, if a hospital had fewer than three eligible discharges in the denominator in general, except as described below, we would not calculate the result for that measure for the hospital. In the most recent public reporting of the AHRQ measures, less than 6 percent of the IPPS hospitals did not have enough eligible discharges to calculate the results for these measures. However, for PSI 5 (foreign object left in body), which identifies ''never events,'' even if a hospital has fewer than three occurrences, these events would be included in the calculation of the hospital's results. For the PSI 90 composite in the alternative approach for Domain 1, we also would propose that the same rules used for the Hospital IQR Program be used to determine whether this composite measure is calculated for a hospital. Specifically, if the number of eligible discharges in the denominator for a given component indicator is fewer than three, the national rate would be substituted for the hospital rate. If the number of eligible discharges for a hospital is fewer than three for every component indicator that makes up the composite, the composite value would not be calculated.

For the HAC Reduction Program, we are proposing to use the same inclusion criteria as used under the Hospital IQR Program for the Domain 2 measures. In order to calculate a Standard Infection Ratio (SIR), a hospital's number of expected HAIs must be ≥1. For hospitals that have an expected number of HAIs < 1, we would insert zero (0) in order to calculate the Domain score. Hospitals that have no ICU and have an active IQR zero ICU beds waiver for Hospital IQR program HAI quality reporting also would receive zero (0) points. If a hospital is eligible to report HAIs, does not have an active Hospital IQR program zero ICU beds waiver, and fails to report to NHSN, it would receive the maximum penalty of 10 points for that measure to calculate the Domain 2 score. (We refer readers to the discussion of scoring under section V.I.3.d. of the preamble of this proposed rule.)

The CDC uses a SIR, which is a summary metric used to track HAIs. The SIR compares the actual number of HAIs at a facility to a national baseline. The number of observed infections is divided by the number of expected infections. The number of expected infections is calculated using event rates from a standard population during a baseline period. (*http://www.cdc.gov/HAI/surveillance/QA_stateSummary.html#a6*). The SIR for CLABSI and CAUTI includes ICU locations, including pediatric and neonatal units. We are proposing to expand both of the populations for these measures to care provided in areas outside of the ICU in the future. (We refer readers to section IX.A. of the preamble of this proposed rule for a discussion of this proposal under the Hospital IQR Program.)

[56] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*.

[57] *http://www.medicare.gov/hospitalcompare/About/HOSInfo/RCD.aspx#ssi*.

(5) Measure Risk-Adjustment Methodology

Section 1886(p)(2)(B)(ii) of the Act requires the Secretary to establish and apply an appropriate risk-adjustment methodology with respect to determining the top quartile of subsection (d) hospitals with respect to HACs subject to the 1 percent payment adjustment. We are proposing to use the existing measure-level risk-adjustment that is already part of the methodology for the individual measures being proposed for Domains 1 and 2 in order to fulfill this requirement. We are proposing to codify the use of this methodology under proposed § 412.172(d). First, with the exception of PSI 5, all of the proposed PSI measures are risk-adjusted and reliability-adjusted. Specifically, risk factors such as the patient's age, gender, comorbidities, and complications would be considered in the calculation of the measure rates so that hospitals serving a large proportion of sicker patients would not be unfairly penalized. We believe that such risk-adjustment is appropriate, pursuant to section 3008 of the Affordable Care Act. We note that the PSI 5 measure (foreign object left in body) is not risk-adjusted. However, a foreign object left in the body constitutes an adverse event that should never occur. Thus, such adverse events cannot be risk-adjusted because these events should not occur, regardless of patient-related or hospital-related characteristics.

We are inviting public comments on the proposed risk-adjustment methodology.

d. Criteria for Applicable Hospitals and Performance Scoring

In general, we are proposing to use a scoring methodology similar to the achievement scoring methodology that is currently used under the Hospital VBP Program. We are proposing to implement a methodology for assessing the top quartile of applicable hospitals for HACs based on performance standards, under which we would score each hospital based on whether they are in the top quartile for each applicable measure and where in the top quartile they fall. In addition, we are proposing to calculate a Total HAC Score for each hospital by summing the hospital's performance score on each measure within a domain to determine a score for each domain, then multiplying each domain score by a proposed weight (Domain 1–AHRQ Patient Safety Indicators 50 percent, Domain 2–CDC NHSN Measures 50 percent), and adding together the weighted domain scores to determine the Total HAC Score. We are proposing to use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals (applicable hospitals) that would be subject to the payment adjustment beginning with discharges on or after October 1, 2014.

With respect to a subsection (d) hospital, we are proposing that CMS will identify the top quartile of all hospitals that are subsection (d) hospitals with respect to their rate of HACs during the applicable period (proposed § 412.172(e)(1)). We are proposing that CMS will use Total HAC scores to identify applicable hospitals and will identify the 25 percent of hospitals with the highest Total HAC scores as applicable hospitals (proposed § 412.172(e)(2)). In addition, we are proposing that CMS will calculate the Total HAC score by weighing Domain 1 score plus Domain 2 equally at 50 percent (proposed § 412.172(e)(3)).

We are proposing that hospital performance under section 1886(p) of the Act would be based on a Total HAC Score, which combines a hospital's results for Domains 1 and 2. As discussed earlier, we are proposing that the Domain 1 score be a combination of each hospital's result for all of the six individual AHRQ measures (Domain 1/Proposed Approach). We presented an alternative, the hospital's result for PSI 90 (Domain 1/Alternative Approach), which also could be used. For Domain 1/Proposed Approach, because hospitals may not have complete data for every AHRQ measure in the domain, we are proposing to use the same methodology as used for the Hospital VBP Program to determine the minimum number of measures with complete data to be included in the calculation of the Outcome Domain. We are proposing to use the following rules to determine the number of AHRQ measures to be included in the calculation for a hospital's Domain 1 score (Table B). In this discussion, ''complete data'' refers to whether a hospital has enough eligible discharges to calculate a rate for a measure. Specifically—

If a hospital did not have complete data for all six of the AHRQ measures, or if a hospital had complete data for fewer than three AHRQ measures, we would not calculate a Domain 1 score for that hospital.

If a hospital had complete data for at least three but fewer than six AHRQ measures, we would calculate a Domain 1 score for that hospital based on the rates of the available measures. The rate of each of these three to five available measures would be equally weighted to contribute to the Domain 1 score. We would exclude the AHRQ measure(s) for which the hospital did not have complete data. Thus, if a hospital had complete data for three AHRQ measures, each measure would contribute to one-third of the hospital's Domain 1 score; if a hospital had complete data for four AHRQ measures, each measure would contribute to one-fourth of the hospital's Domain 1 score; if a hospital had complete data for five AHRQ measures, each measure would contribute to one-fifth of the hospital's Domain 1 score.

If a hospital had complete data for at least three but fewer than six AHRQ measures, we would calculate a Domain 1 score for that hospital based on the rates of the available measures. The rate of each of these three to five available measures would be equally weighted to contribute to the Domain 1 score. We would exclude the AHRQ measure(s) for which the hospital did not have complete data. Thus, if a hospital had complete data for three AHRQ measures, each measure would contribute to one-third of the hospital's Domain 1 score; if a hospital had complete data for four AHRQ measures, each measure would contribute to one-fourth of the hospital's Domain 1 score; if a hospital had complete data for five AHRQ measures, each measure would contribute to one-fifth of the hospital's Domain 1 score.

If a hospital had complete data for all six AHRQ measures, we would calculate a Domain 1 score for that hospital based on the rates of all six measures. The rate of each of these six measures would be equally weighted to contribute to the Domain 1 score. Thus, each measure would contribute to one-sixth of the hospital's Domain 1 score.

TABLE B—OVERALL DESCRIPTION OF HOW MEASURES IN DOMAIN 1/PROPOSED APPROACH WOULD BE HANDLED IN TOTAL HAC SCORE

Domain 1—Proposed Approach: Six individual AHRQ Patient Safety Indicators (PSIs)	
Number of PSIs with complete data*	Rules for calculating Domain 1—Option 1 score
< 3	• Do not calculate Domain 1 score or Total HAC Score for hospital.
3 to 5	• Include PSIs with complete data in calculation of Domain 1 score. • Exclude PSIs without complete data. • Weight each PSI equally.
6	• Include all 6 PSIs in calculation of Domain 1 score and Total HAC score.

TABLE B—OVERALL DESCRIPTION OF HOW MEASURES IN DOMAIN 1/PROPOSED APPROACH WOULD BE HANDLED IN TOTAL HAC SCORE—Continued

Domain 1—Proposed Approach: Six individual AHRQ Patient Safety Indicators (PSIs)	
Number of PSIs with complete data*	Rules for calculating Domain 1—Option 1 score
	• Weight each PSI equally.

*Complete data = A hospital having enough cases to calculate the risk-adjusted and reliability-adjusted rate for an AHRQ PSI.

The calculation of the SIR for the CDC measures requires the facility have >1 predicted HAI event. The predicted number of events is calculated using the national HAI rate and the observed number of the specific HAIs. In the event an SIR cannot be calculated because the facility has <1 predicted infection, Domain 1 scores exclusively will be used to calculated a HAC score. In other words, we would exclude from the overall HAC score calculation any measure for which an SIR cannot be calculated for the reason set out above.

Because of the differences among the measures proposed for the HAC Reduction Program and the distribution of measure results, simply adding up the measure results to calculate the domain or Total HAC Scores would make the scores less meaningful to hospitals and the general public. As a result, we are proposing that points be assigned to hospitals' performance for each measure. This approach aligns with the Hospital VBP Program for measuring hospital achievement. In particular, the Hospital VBP Program assigns up to 10 points for each measure based on a hospital's result of that measure for a given time period. We note that, for the HAC Reduction Program, unlike the Hospital VBP Program where a higher score means better performance, the more points a hospital receives on a measure correspond with a poorer score. For the HAC Reduction Program, we are proposing a slightly different methodology for scoring points, depending on the specific measure (Table C). Specifically—

- For PSI 5 (Volume of foreign object left in body) in Domain 1—Proposed Approach, the measure results are frequency counts.
  - ○ Because this measure captures the number of never events, which should never happen, regardless of patient or hospital characteristics, we are proposing to assign 10 points, the maximum number of points, if the hospital had at least one occurrence.
  - ○ If a hospital had no occurrence for this measure, we would assign zero points.
- For PSI 3, 6, 10, 12, and 15 in Domain 1—Proposed Approach, point assignment for each measure would be based on the rate of occurrence for that measure.
  - ○ If a hospital's rate is within the worse performing quartile for a measure, we would assign 1 to 10 points to the hospital for that measure. The proposed rules for determining the number of points to be assigned are discussed later.
  - ○ If a hospital's rate is not within the worse performing quartile for a measure, we would assign zero points to the hospital for that measure.
- For the AHRQ Patient Safety for Selected Condition (PSI 90) composite in Domain 1—Alternative Approach, point assignment would be based on a hospital's score for the composite measure.
  - ○ If a hospital's result is within the worse performing quartile for a measure, we would assign 1 to 10 points to the hospital for this composite measure. The proposed rules for determining the number of points to be assigned are discussed later.
  - ○ If a hospital's result is not within the worse performing quartile, we would assign zero points to the hospital for this composite measure.
- For the CDC NHSN measures in Domain 2, point assignment for each measure would be based on the SIR for that measure.
  - ○ If a hospital's SIR is within the worse performing quartile for a measure, we would assign 1 to 10 points to the hospital for that measure. The proposed rules for determining the number of points to be assigned are discussed later.
  - ○ If a hospital's SIR is not within the worse performing quartile for a measure, we would assign zero points to the hospital for that measure.

TABLE C—CALCULATION OF DOMAIN 1 AND 2 MEASURES

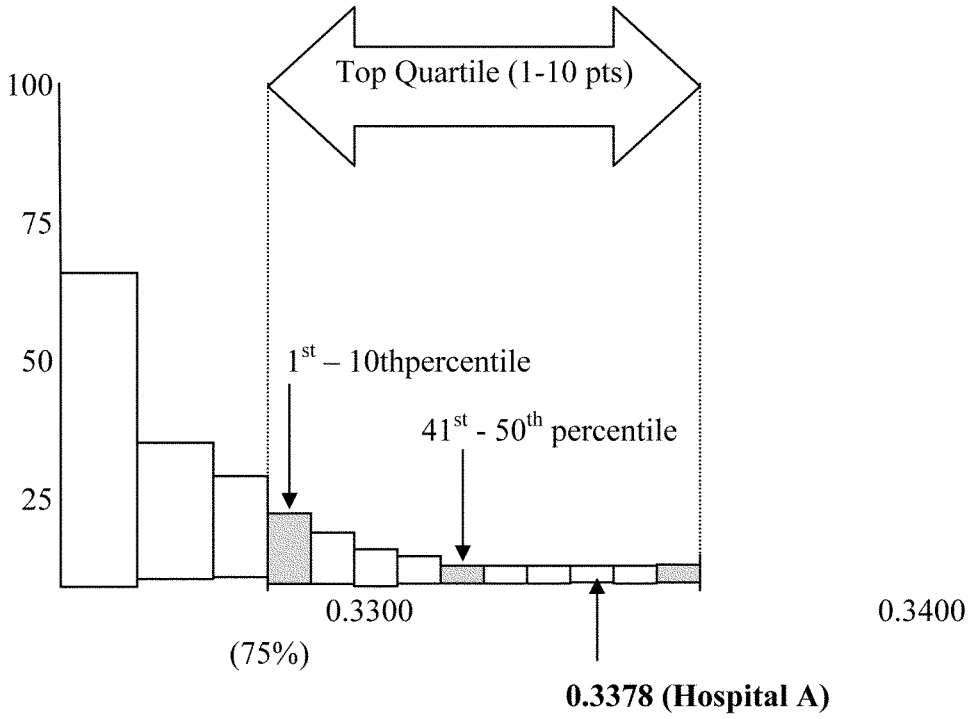
Measure name	Measure result	Scenario	Individual measure score (points)
PSI–5*	Frequency count	Occurrence = 0	0
		Occurrence ≥ 1	10
PSIs 3, 6, 10, 12, 15**	Rates***	Rate ≥ 75%	1–10
		Rate < 75%	0
PSI 90	Weighted average of rates of component indicators.	Composite value ≥ 75%	1–10
		Composite value < 75%	0
CDC NHSN measure	Standard Infection Ratio (SIR)	SIR ≥ 75%	1–10 (see Figure A)
		SIR < 75%	0

*PSI–5 is the Volume of foreign object left in the body measure, developed by AHRQ.
**PSI–3 is Pressure ulcer rate; PSI–6 is Iatrogenic Pneomothorax; PSI–10 is Postoperative physiological and metabolic derangement rate; PSI–12 is Postoperative pulmonary embolism or deep vein thrombosis rate; PSI–15 is Accidental puncture and laceration rate.
***These measure rates are risk-adjusted and reliability-adjusted.

For all the proposed measures for the HAC Reduction Program, with the exception of PSI 5, we are proposing the following rules to determine the number of points assigned to a measure that is within the top (or worse performing) quartile: Based on the distribution of measure results within the top (or worse performing) quartile of a measure, we would divide the measure results into percentiles. Figure A shows an example for point assignment for PSI 3 (Pressure ulcer rate). In this example, if a hospital's rate for PSI 3 is between 0.3000 and 0.3400, it is within the top (or worse performing) quartile. For Hospital A, the rate for PSI 3 is 0.3378. As a result, Hospital A is subject to 1 to 10 points for PSI 3. Based on the distribution for PSI 3 rates for all the hospitals in the top quartile, we would divide the results into percentiles in increments of 10 with the lowest percentile ranges meaning better

performance within the top quartile. Hospitals with PSI 3 rates within the lowest tenth percentile of the top quartile would be given one point; those with PSI 3 rates within the second lowest percentile range (between the 10th and 20th percentile) of the top quartile would be given 2 points, etc. Because Hospital A's rate for PSI 3 is within the eighth percentile range (between the 70th and 80th percentile), we would assign 8 points to this PSI 3 measure for Hospital A.

Figure A.--Example of Point Assignment for Hospital A with PSI-3 (Pressure ulcer rate) Rate = 0.3378



POINT ASSIGNMENT FOR HOSPITAL A'S PSI–3 SCORE:

If Hospital A's PSI–3 rate falls into this percentile above 75%	Then assign this number of points
1st–10th	1
11th–20th	2
21st–30th	3
31st–40th	4
41st–50th	5
51st–60th	6
61st–70th	7
71st–80th	8
81–90th	9
91st–100th	10

For Domain 2, we would obtain measure results that hospitals submitted to the CDC NHSN for the Hospital IQR Program. The CDC HAI measures capture adverse events that occurred within intensive care units (ICUs), including pediatric and neonatal units. For the Hospital IQR Program, hospitals that elected to participate in the reporting program (that is, had an active IQR pledge), but did not have ICUs, can apply for an ICU waiver so that they would not be subject to the 2-percent payment reduction for nonsubmission of quality reporting data.

In the second quarter of 2012, among the 3,321 IPPS hospitals with an active IQR pledge for data submission, 377 (or 10.1 percent) applied and received an ICU waiver. At the same time, 2,939 hospitals (88.5 percent) of the IPPS hospitals did not have an ICU waiver and submitted data for the CDC HAI CLABSI measure, while 4 hospitals (0.1 percent) that had no ICU waiver failed to submit data to the NHSN. For the same quarter, of the 3,321 IPPS hospitals with an active IQR pledge, 2,935 (88.4 percent) that did not have an ICU waiver submitted data for the CDC HAI CAUTI measure, whereas 8 hospitals (0.2 percent) did not submit data. Because data availability for the two proposed CDC HAI measures impact the score for Domain 2 and eventually the Total HAC Score, CMS aims to encourage hospitals with an ICU that did not submit data to begin data submission, and to reward hospitals that have already submitted data to continue data submission for all the CDC HAI measures. To this end, we are proposing the following rules (Figure B):

- If a hospital had an ICU waiver for the CDC HAI measures, we would use only the Domain 1 score to calculate its Total HAC Score.
- If a hospital did not have an ICU waiver for a CDC HAI measure:
  - ○ If the hospital did not submit data for the CDC HAI measures, we would assign 10 points to that measure for that hospital.
  - ○ If the hospital did submit data for at least one CDC NHSN measure:
    - ▪ If there are complete data (that is, enough adverse events to calculate the SIR) for at least one measure, we would use those data to calculate a Domain 2 score and use the hospital's Domain 1 and Domain 2 scores to calculate the Total HAC Score.
    - ▪ If there are not enough adverse events to calculate the SIR for any of the measures, we would use only the

hospital's Domain 1 score to calculate its Total HAC Score.

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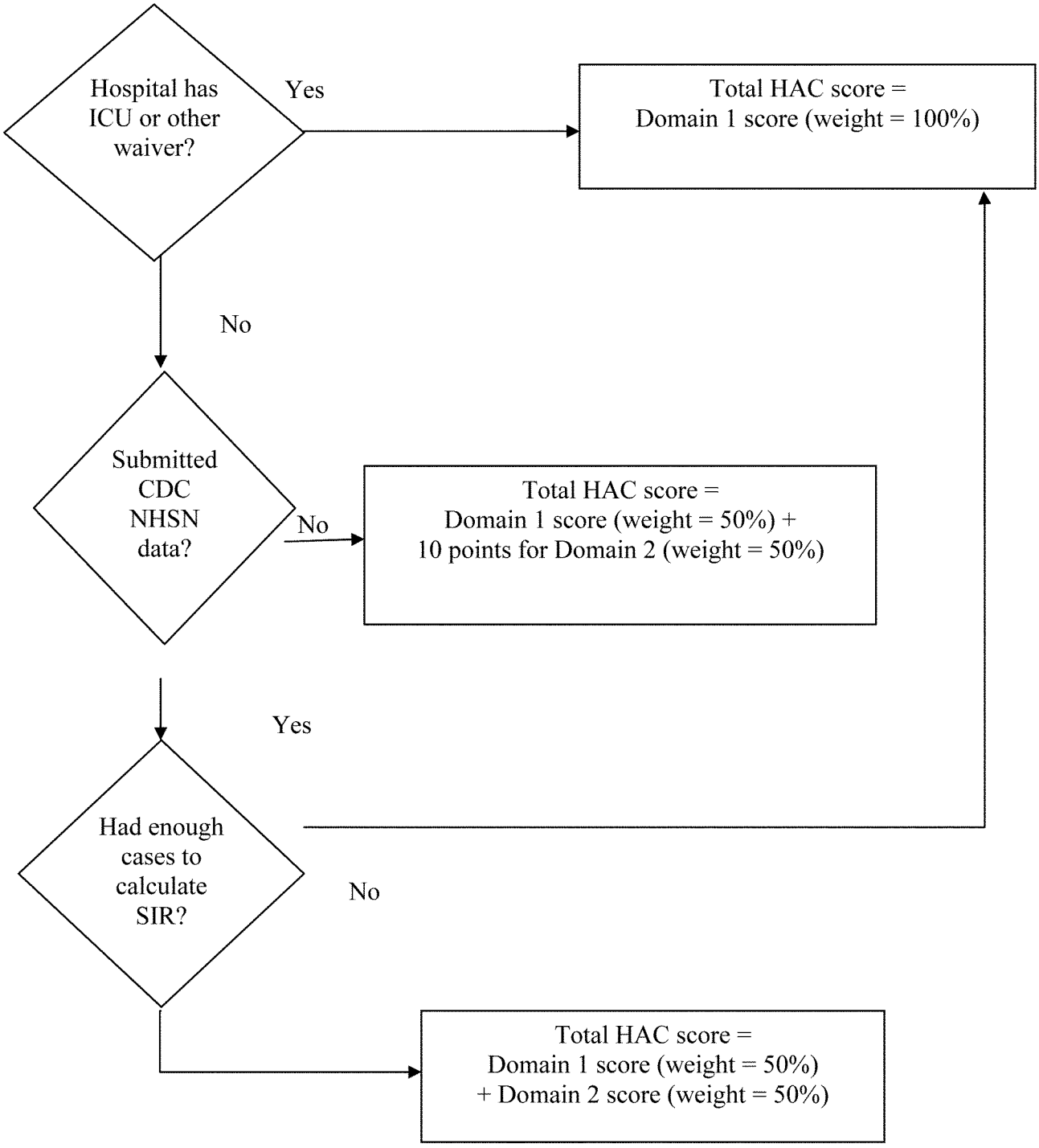
Figure B. Calculation of Total HAC Score for Domain 2 CDC NHSN Measures



Key:
Domain 1 = AHRQ Patient Safety Indicators
Domain 2 = CDC NHSN measures

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As discussed earlier, if a hospital has complete data for the measures in both Domain 1 and Domain 2, the scores of the two domains would contribute equally to the Total HAC Score. In the case of Domain 1—Proposed Approach, if a hospital has complete data for at least three measures in Domain 1 and at least one measure in Domain 2, its Domain 1 score and Domain 2 score would contribute equally to its Total HAC Score. However, if a hospital has complete data for fewer than three measures in Domain 1 and at least one measure in Domain 2, its Total HAC Score would depend entirely on its Domain 2 score. Similarly, if a hospital has complete data for at least three of the measures in Domain 1 but none of the measures in Domain 2, its Total HAC Score would be based entirely on its Domain 1 score. If a hospital does not have complete data for at least three measures in Domain 1 and at least one measure in Domain 2, we would not calculate a Total HAC Score for this hospital.

In the case of Domain 1—Alternative Approach, if a hospital has enough data to calculate PSI 90 for Domain 1 and complete data for at least one measure in Domain 2, the scores of the two domains would contribute equally to the Total HAC Score. However, if a hospital does not have enough data to calculate PSI 90 for Domain 1 but it has complete data for at least one measure in Domain 2, its Total HAC Score would depend entirely on its Domain 2 score. Similarly, if a hospital has complete data to calculate PSI 90 in Domain 1 but none of the measures in Domain 2, its Total HAC Score would be based entirely on its Domain 1 score. If the hospital does not have complete data to calculate PSI 90 for Domain 1 or any of the measures in Domain 2, we would not calculate a Total HAC Score for this hospital.

We are inviting public comments on this proposed scoring methodology. In addition, we are inviting public comments on alternate methodologies for scoring hospitals and determining most accurately those hospitals that are in the top quartile for the selected HACs. For example, instead of awarding points for each measure only to those hospitals that fall in the top quartile for that specific measure, an alternative option would be to award points to each hospital for each measure in deciles from the best performing hospital to the worst performing hospital. Another example would be to award points in deciles for each measure between the median rate for a particular measure and the rate of the worst performing hospital. We are seeking to identify hospitals that are in the top quartile for all of the HACs combined and are soliciting public comments on approaches to best identify this group of hospitals.

e. Reporting Hospital-Specific Information, Including the Review and Correction of Information

(1) Confidential Reports to Applicable Hospitals

Section 1886(p)(5) of the Act requires the Secretary to provide confidential reports to the applicable hospitals with respect to HACs. To meet the requirements under section 1886(p)(5) of the Act, we are proposing that confidential reports for the HAC Reduction Program contain information related to claims-based measure data for the PSI measures, the domain score for each domain, and the Total HAC Score. We note that, although we are proposing to use chart-abstracted measures in the HAC Reduction Program, such information will be contained in the reports hospitals currently receive as part of the Hospital IQR Program and can be reviewed and corrected through the process specified for that program. We believe that this method would reduce the burden on hospitals, by alleviating the need to correct data present in two different programs. However, we welcome any public comments and suggestions on this proposal.

(2) Availability of Information to the Public

Section 1886(p)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding HAC rates of each subsection (d) hospital'' under the HAC Reduction Program. Section 1886(p)(6)(C) of the Act requires the Secretary to post the HAC information for each applicable hospital on the *Hospital Compare* Web site in an easily understood format. Section 1886(p)(6)(B) of the Act also requires the Secretary to ''ensure that an applicable hospital has the opportunity to review, and submit corrections for, the HAC information to be made public for each hospital.''

To meet the requirements under section 1886(p)(6)(C) of the Act, we are proposing that the following information would be made public on the *Hospital Compare* Web site relating to the HAC Reduction Program: (1) Hospital scores with respect to each measure; (2) each hospital's domain specific score; and (3) the hospital's Total HAC Score. However, because this is a new program, we are inviting public comments and suggestions on other information to be posted on the *Hospital Compare* Web site.

(3) Review and Correction of Information

Section 1886(p)(6)(B) of the Act requires the Secretary to ensure that each hospital has the opportunity to review and submit corrections for the information to be made available to the public with respect to each hospital under section 1886(p)(6)(A) of the Act prior to such information being made available to the public. We are proposing that hospitals be allowed to review and correct the following information as part of the HAC Reduction Program prior to it being made available to the public: the claims-based measures in Domain 1; the point allocations for the measures in each domain; the domain scores; and the Total HAC Score.

For the FY 2015 HAC Reduction Program, we are proposing to use individual HAC measures consisting of CDC HAI measures as well as claims-based measures. Further, we are proposing for the HAC Reduction Program that hospitals have an opportunity to review and correct chart abstracted data and claims based data for each measure through the processes discussed below. These individual measures will be used to calculate the domain and Total HAC Score, which would determine those applicable hospitals within the top quartile, or those hospitals with the highest number of HACs. We also are proposing that hospitals have the opportunity to review and submit corrections on its Domain and Total HAC Score for the HAC Reduction Program, which is also described below.

(a) Chart-Abstracted Measures (Domain 2—CDC HAI Measures)

We are proposing to use the same process that hospitals currently have to review and correct data submitted on the Hospital IQR Program chart-abstracted measures to review and correct chart-abstracted measures in Domain 2 under the HAC Reduction Program. Under this proposed process, hospitals would continue to have the opportunity to review and correct data they submit on all Hospital IQR Program chart abstracted measures, whether or not the measure was adopted as a measure for the HAC Reduction Program. We are proposing to use the Hospital IQR Program's data submission, review, and correction processes, which would allow for review and correction of data on a continuous basis as data are being submitted for the Hospital IQR Program,

which in turn would allow hospitals to correct data used to calculate the Total HAC Score for those hospitals that participate in both the Hospital IQR Program and the HAC Reduction Program. We believe this process would satisfy the requirement in section 1886(p)(6) of the Act to allow hospitals to review and submit corrections for information that will be made public with respect to each hospital. Under the Hospital IQR Program, hospitals currently have an opportunity to submit, review, and correct any of the chart-abstracted information for the full 4 ½ months following the last discharge date in a calendar quarter. Hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule to identify errors and resubmit data before the quarterly submission deadline. Users may view and make corrections to the data that they submit starting immediately following submission. The data are populated into reports that are updated immediately with all data that have been submitted successfully. Hospitals are able to view a report each quarter which shows the numerator, denominator, and percentage of total for each Clinical Measure Set and Stratum. That report contains the hospital's performance on each measure set/stratum submitted quarterly by CDC on behalf of hospitals to CMS'QIO Clinical Warehouse. We believe that 4 ½ months is sufficient time for hospitals to be able to submit, review data, make corrections to the data, and view their percentage of total, or measure rate, on each Clinical Measure Set/Strata for use in both the Hospital IQR Program and the HAC Reduction Program. In addition, because this process is familiar to most hospitals, use of this existing framework reduces the burden that could have been placed on hospitals that participate in the Hospital IQR Program if they had to learn a new process for submitting chart-abstracted data for the HAC Reduction Program. Subsequent to the period during which hospitals could review and correct data and measure rates for chart-abstracted measures as specified, they would have no further opportunity to correct such data or measure rates. We are proposing that once the hospital had an opportunity to review and correct quarterly data related to chart abstracted measures submitted in the Hospital IQR Program, we would consider that the hospital had been given the opportunity to review and correct the data for the HAC Reduction Program. We are proposing to use these data to calculate the measure scores for purposes of the HAC Reduction Program, and these measure scores would be used to calculate domain and Total HAC Scores for the HAC Reduction Program without further review and correction. We invite public comment on this proposal.

(b) Claims Based Measures (Domain 1 AHRQ PSI Measures)

For purposes of the HAC Reduction Program for FY 2015, we are proposing to calculate Domain 1 measure rates using the 2-year applicable period for the FY 2015 payment determination that spans from July 1, 2011 through June 30, 2013, data sources, and apply the minimum number of discharges criteria shown in Table B for each hospital as proposed. We intend to make this information available to the public, consistent with the requirements of section 1886(p)(6)(B) of the Act, as part of the FY 2015 rulemaking process, in addition to posting this information on the *Hospital Compare* Web site in a subsequent release.

We are proposing to provide hospitals an opportunity to review and submit corrections for claim-based measures using a process similar to the process currently used for posting results on the *Hospital Compare* Web site, which is also the process currently used in the Hospital Readmissions Reduction Program. Below, we are proposing the details regarding the process for hospitals to review and submit corrections to their data score prior to making this information available to the public in rulemaking and on the *Hospital Compare* Web site.

For FY 2015, for the HAC Reduction Program, we are proposing to deliver confidential reports and accompanying confidential discharge level information to hospitals as defined in section V.I.3.d. of the preamble of this proposed rule. These reports would be delivered in hospitals' secure QualityNet accounts. The information in the confidential reports and accompanying confidential discharge-level information would be calculated using the claims information we had available approximately 90 days after the last discharge date in the applicable period, which is when we would create the data extract for the calculations. The discharge-level information accompanying the Domain 1 PSI measure rates would include the risk factors for the discharges that factor into the calculation of the Total HAC Score used to determine the top quartile of applicable hospitals, dates of admission and discharge, discharge characteristics, and other information relevant to the measure calculations, that is, exclusions. Our intent in providing this information is twofold: (1) To facilitate hospitals' verification of the Domain 1 PSI measure calculations we provide during the review and correction period based upon the information we had available at the time our data extract was created; and (2) to facilitate hospitals' quality improvement efforts with respect to the PSI measures.

The review and correction process we are proposing for claims based measures in Domain 1 would not include submitting additional corrections related to the underlying claims data we used to calculate the measures for Domain 1, or adding new claims to the data extract we used to calculate the measures used in Domain 1. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of this program, we would calculate the measures in Domain 1 using a static snapshot (data extract) taken at the conclusion of the 90-day period following the last date of discharge used in the applicable period. We recognize that under our current timely claims filing policy, hospitals have up to 1 year from the date of discharge to submit a claim to us. However, in using claims data to calculate measures for this program, we are proposing to create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2013, we would create the data extract on September 30, 2013, and use that data to calculate the claims based measures for that applicable period. Hospitals would then receive the Domain 1 Score in their confidential reports and accompanying discharge-level information, and they would have an opportunity to review and submit corrections for the calculations of the measures in Domain 1. As we stated above, hospitals would not be able to submit corrections to the underlying claims snapshot used for the Domain 1 measure calculations after the extract date, and also would not be able to add claims to this data set. Therefore, we would consider hospitals' claims data to be complete for purposes of calculating the Domain 1 for the HAC Reduction Program at the conclusion of the 90-day period following the last date of discharge used in the applicable period. We considered a number of factors in determining that a 90-day ''run-out'' period is appropriate for purposes of calculating claims based measures.

First, we seek to provide timely quality data to hospitals for the purpose of quality improvement and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals based on their performance on measures as close in time to the performance period as possible. Finally, with respect to claims-based measures, we seek to have as complete a data set as possible, recognizing that hospitals have up to 1 year from the date of discharge to submit a claim under CMS' timely claims filing policy. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations, as well as program, populate, and deliver the confidential reports and accompanying data to be delivered to hospitals. We also are aware that hospitals would prefer to receive the calculations to be used for the HAC Reduction Program as soon as possible. Because several months lead time is necessary after acquiring the data to generate these claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to hospitals sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay both for hospitals and for us to deliver timely calculations to hospitals for quality improvement and transparency, and ultimately timely readmission adjustment factors for purposes of this program. Therefore, we are proposing to extract the data needed to calculate the Domain 1 for this program 90 days after the last date of discharge for the applicable period so that we can balance the need to provide timely program information to hospitals with the need to calculate the claims based measures using as complete a data set as possible. We note that, under the proposed process, hospitals would retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies. However, we emphasize that the administrative claims data used to calculate the Domain 1 measures and the resulting Domain Score reflect the state of the claims at the time of extraction from CMS' Common Working File. Under the proposed process, a hospital's opportunity to submit corrections to the calculation of the Total HAC Score ends at the conclusion of the review and correction period.

(c) Total HAC Score

We are proposing to provide hospitals with a period of 30 days to review and submit corrections for their Total HAC Scores for the HAC Reduction Program. This 30-day period would begin when the hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. This proposed requirement will enable us to evaluate correction requests and provide decisions on those requests in a timely manner.

We believe that this proposed review and corrections process will ensure that hospitals are able to fully and fairly review their domain and Total HAC Score. We view the review and corrections process as a means to ensure that the information posted on the *Hospital Compare* Web site is accurate. We are inviting public comments on the proposed review and corrections process for the HAC Reduction Program. Based on previous experience with public reporting of measures under the Hospital IQR Program, and review and correction processes currently in place for the Hospital Readmission Reduction Program and the Hospital VBP Program, we believe this 30-day period allows enough time for hospitals to review their data and notify us of calculation errors, and for us to incorporate appropriate corrections to the HAC calculations prior to making the data available to the public. We are proposing that the Total HAC Score would be made available to the public via *Hospital Compare* Web site after the review and correction period. During the review and correction period, hospitals should notify us of suspected errors in their Total HAC Score using the technical assistance contact information provided in their confidential reports.

During the 30-day review and correction process for the Total HAC Score, if a subsection (d) hospital suspects that discrepancies exist in our application of the HAC scoring methodology (assignment of points to measures, domain scoring, domain weighting), it should notify us during the review and correction period using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. If we confirm that we made an error in creating the data extract or in calculating the Total HAC Score, we would correct the calculations, issue new confidential reports to affected subsection (d) hospitals, and then publicly report the corrected Total HAC Score. However, if the errors take more time than anticipated to correct, we would notify hospitals that corrected HAC Scores will be made available through delivery of confidential reports followed by a second 30-day review and correction period, subsequent publication, and posting on *Hospital Compare* Web site. In addition, we are proposing that any corrections to a hospital's Total HAC Score would then be used to recalculate a hospital's quartile under section 1886(p)(2)(B)(i) of the Act in order to determine the hospital's adjustment factor in accordance with section 1886(p)(2)(B)(ii) of the Act.

We believe that this proposed process would fulfill the statutory requirements at section 1886(p)(2)(B), section 1886(p)(6)(B), and section 1886(p)(6)(C) of the Act. We further believe that the proposed process would allow hospitals to review and correct their Total HAC Score.

We are proposing to codify this review and correction process at proposed § 412.172(f). In summary, we are specifying that CMS will make information available to the public regarding HAC rates of all hospitals described in section 1886(d)(1)(B) of the Act, including hospitals in Maryland paid under section 1814(b)(3) of the Act, under the HAC Reduction Program (proposed paragraph (f)). To ensure that a hospital has the opportunity to review and submit corrections for its HAC rates for the applicable conditions for a fiscal year that are used to determine its total hospital acquired conditions score, we are specifying that CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its total hospital acquired conditions score (proposed paragraph (f)(2)). Hospitals will have a period of 30 days after receipt of the information provided to review and submit corrections for the hospital acquired conditions domain score for each condition that are used to calculate the Total HAC score for the fiscal year (proposed paragraph (f)(2)). The administrative claims data used to calculate a hospital's total hospital acquired conditions score for the conditions for a fiscal year will not subject to review and correction (proposed paragraph (f)(3)). CMS will post the total hospital acquired condition score for the applicable conditions for a fiscal year for each applicable hospital on the Hospital Compare Web site (proposed paragraph (f)(4)).

f. Limitation on Administrative and Judicial Review

Section 1886(p)(7) of the Act provides that there will be no administrative or judicial review under Section 1869 of the Act, under Section 1878 of the Act, or otherwise for any of the following:

- The criteria describing an applicable hospital under section 1886(p)(2)(A) of the Act.
- The specification of hospital acquired conditions under section 1886(p)(3) of the Act.
- The specification of the applicable period under section 1886(p)(4) of the Act.
- The provision of reports to applicable hospitals under section 1886(p)(5) of the Act.
- The information made available to the public under section 1886(p)(6) of the Act.

We are proposing to include these statutory provisions under proposed § 412.172(g). We note that section 1886(p)(6) of the Act requires the Secretary to make information available to the public regarding HAC scores of each applicable hospital under the HAC Reduction Program. Section 1886(p)(6)(B) of the Act also requires the Secretary to ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made available to the public, prior to that information being made public. We believe that the review and correction process explained above will provide hospitals with the opportunity to correct data prior to its release on the *Hospital Compare* Web site.

J. Payments for Direct Graduate Medical Education (GME) Costs (§§ 412.106 and 413.75 through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the hospital inpatient prospective payment system (IPPS) for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. Regulations implementing these changes are discussed in the November 24, 2010 final rule (75 FR 72133) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53416).

2. Proposed Inclusion of Labor and Delivery Days in the Calculation of Medicare Utilization for Direct GME Purposes and for Other Medicare Inpatient Days Policy

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53411), we discussed Medicare's policies with respect to the treatment of labor and delivery services in the calculation of the Medicare DSH payment adjustment. We noted that, in the FY 2010 IPPS/LTCH PPS final rule, we made a change to include, in the DPP of the Medicare DSH payment adjustment, all patient days associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as an inpatient, regardless of whether the patient days are associated with patients who occupied a routine bed prior to occupying an ancillary labor and delivery bed. We stated that we made the change because the costs associated with labor and delivery patient days are generally payable under the IPPS.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53413), we finalized a policy extending our current approach of including labor and delivery patient days in the DPP of the Medicare DSH payment adjustment to our rules for bed counting for purposes of both the IME payment adjustment and the Medicare DSH payment adjustment. We stated that if a patient day is counted for DSH payment purposes because the services furnished are generally payable under the IPPS, the bed in which the services are furnished also should be considered to be available for IPPS-level care. To implement this policy, we amended the regulations at 42 CFR 412.105(b)(4) to remove from the list of excluded beds those beds associated with ''ancillary labor/delivery services.'' This change was effective for cost reporting periods beginning on or after October 1, 2012.

In response to our proposal in the FY 2013 IPPS/LTCH proposed rule to include labor and delivery bed days as available bed days for DSH and IME payment adjustment purposes, commenters noted that if these days are considered inpatient days, they also should be considered patient days for purposes of allocating direct GME payments. However, the Medicare cost report currently does not allow for labor

and delivery patient days to be counted in the direct GME patient load. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53413), we stated that we would undertake further review to determine whether it was necessary to make any changes in the manner in which patient days are reported on the Medicare cost report and whether these labor and delivery patient days should be excluded or included from the calculation of the Medicare patient load.

For this FY 2014 IPPS/LTCH PPS proposed rule, we have analyzed the calculation of the Medicare patient load and the cost reporting implications. Direct GME payments are calculated using three variables: the hospital's per resident amount; the number of FTE residents a hospital is training subject to its FTE cap and the rolling average; and the hospital's Medicare patient load. ''Medicare patient load'' is defined at 42 CFR 413.75(b) as ''with respect to a hospital's cost reporting period, the total number of hospital inpatient days during the cost reporting period that are attributable to patients for whom payment is made under Medicare Part A divided by total hospital inpatient days. In calculating inpatient days, inpatient days in any distinct part of the hospital furnishing a hospital level of care are included and nursery days are excluded.'' We agree with the commenters who stated that because labor and delivery days are considered inpatient days for DSH purposes, they also should be considered inpatient days for purposes of determining the Medicare share for direct GME payments. We believe that the best way to calculate a hospital's Medicare patient load or the ''Medicare utilization'' (the term we will use for the remainder of this section) is to include *all* of the hospital's inpatient days. Consistent with the inpatient day counting rules for DSH as clarified in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we are proposing that patient days associated with maternity patients who were admitted as inpatients and were receiving ancillary labor and delivery services at the time the inpatient routine census is taken, regardless of whether the patient actually occupied a routine bed prior to occupying an ancillary labor and delivery bed and regardless of whether the patient occupies a ''maternity suite'' in which labor, delivery recovery, and postpartum care all take place in the same room, will be included in the Medicare utilization calculation. We understand that including labor and delivery inpatient days in the Medicare utilization ratio invariably would reduce direct GME payments because the denominator of the ratio, which includes the hospital's total inpatient days, would usually increase at a higher rate than the numerator of the ratio. However, because the Medicare utilization ratio is a comparison of a hospital's *total* Medicare inpatient days to its *total* inpatient days, we believe that revising the ratio to include labor and delivery days is appropriate because they are inpatient days and, therefore, should be counted as such. Therefore, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2013, for purposes of applying the Medicare utilization ratio, we would include labor and delivery inpatient days in the numerator (to the extent that there are any labor and delivery inpatient days associated with Medicare beneficiaries), and all labor and delivery inpatient days (associated with all inpatients of the hospital) in the denominator. In order to implement this proposed change, we note that we would need to amend the applicable cost report worksheets and instructions (in particular, Worksheet S–3, Part 1) to allow for the inclusion of labor and delivery inpatient days in the Medicare utilization ratio.

In addition to direct GME, which uses the ratio of Medicare inpatient days to total inpatient days to determine payment, this proposal also impacts other Medicare policies where either the number of inpatient days or a ratio of Medicare inpatient days to total inpatient days is used to determine eligibility or payment. Regarding eligibility, for example, including labor and delivery days as inpatient days could affect a hospital's eligibility for SCH status. A hospital can be classified as an SCH if it is located more than 35 miles from other like hospitals or is located in a rural area (as defined at § 412.64 of the regulations) and meets one of the conditions listed in the regulations at § 412.92(a). In determining whether a nearby hospital is a like hospital, CMS compares the total inpatient days of the SCH applicant hospital with the total inpatient days of the nearby hospital. If the total inpatient days of the nearby hospital are greater than 8 percent of the total inpatient days reported by the SCH applicant hospital, the nearby hospital is considered a like hospital for purposes of evaluating the applicant hospital's eligibility for SCH status. Therefore, including labor and delivery days as inpatient days may impact the count of inpatient days for both the SCH applicant hospital and the nearby hospital and may affect the applicant hospital's eligibility for SCH status. However, this proposal would not impact Medicare payments calculated on a reasonable cost basis for routine inpatient services, which are apportioned in accordance with 42 CFR 413.53(a)(1).

In summary, we are proposing to include labor and delivery days as inpatient days in the Medicare utilization calculation, effective for cost reporting periods beginning on or after October 1, 2013.

3. Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency cap slots after a hospital that trained residents in an approved medical residency program(s) closes. Specifically, section 5506 amended the Act by adding a subsection (vi) to section 1886(h)(4)(H) and modifying the language at section 1886(d)(5)(B)(v) to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is March 23, 2008). In the CY 2011 OPPS/ASC final rule with comment period issued in the **Federal Register** on November 24, 2010 (75 FR 72212), we established regulations and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from a hospital that closed. The procedures we established apply both to teaching hospitals that closed after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that closed after August 3, 2010. We made clarifications and revisions to the policy regarding applications under section 5506 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53477).

b. Notice of Closure of a Teaching Hospital

This notice serves to notify the public of the closure of a teaching hospital, and to initiate another round of the section 5506 application and selection process. This round would be the fourth round of the section 5506 (''Round 4'') application and selection process. The following closed teaching hospital is part of the Round 4 application process under section 5506:

Provider No.	Provider name	City and state	CBSA Code	Terminating date	IME Cap (including +/− MMA Sec. 422 [1] adjustment)	Direct GME Cap (including +/− MMA Sec. 422 [1] adjustment)
330002	Peninsula Hospital Center.	Far Rockaway, NY.	35644	April 9, 2012	28.31 + 0.01 section 422 increase = 28.32 [2].	28.31 + 8.03 section 422 increase = 36.34 [3]

[1] Section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, redistributed unused residency slots effective July 1, 2005.

[2] Peninsula Hospital Center's 1996 IME FTE cap is 28.31. Under section 422 of the MMA, the hospital received an increase of 0.01 to its IME FTE cap: 28.31 + 0.01 = 28.32. We note that, under 42 CFR 412.105(d)(4), IME FTE cap slots associated with an increase received under section 422 of the MMA are to be paid using a special multiplier of 0.66.

[3] Peninsula Hospital Center's 1996 direct GME FTE cap is 28.31. Under section 422 of the MMA, the hospital received an increase of 8.03 to its direct GME FTE cap: 28.31 + 8.03 = 36.34. We note that under 42 CFR 413.77(g), direct GME FTE cap slots associated with an increase received under section 422 of the MMA are to be paid using the appropriate locality-adjusted national average per resident amount (PRA).

c. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals wishing to apply for and receive slots from the above hospital's FTE resident caps must submit applications directly to the CMS Central Office no later than July 25, 2013. Unlike in the first 2 rounds of section 5506, under this round, hospitals need not submit applications to their respective CMS Regional Office. The mailing address for the CMS Central Office is included on the application form. Applications must be received, not postmarked, by July 25, 2013. After an applying hospital sends a hard copy of a section 5506 application to the CMS Central Office mailing address, we strongly encourage it to send an email to: *ACA5506application@cms.hhs.gov*. In the email, the hospital should state: ''I am sending this email to notify CMS that I have mailed a hard copy of a section 5506 application to CMS.'' An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify CMS Central Office that a hard copy application has been mailed to CMS Central Office.

In the CY 2011 OPPS/ASC final rule with comment period, we did not establish a deadline by when CMS would issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we will review all applications received by the deadline, and will notify applicants of our determinations as soon as possible.

We refer readers to the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dgme.html* to download a copy of the application form (Section 5506 CMS Application Form) that hospitals are to use to apply for slots under section 5506. We also refer readers to this same Web site to access a copy of the CY 2011 OPPS/ASC final rule with comment period, a copy of the FY 2013 IPPS/LTCH PPS final rule (CMS–1488–F, 77 FR 53434 through 53447), and a list of additional section 5506 guidelines for an explanation of the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

4. Payments for Residents Training in Approved Residency Programs at CAHs

a. Background

Recently, we have received questions regarding how CMS would make payment for residency training occurring in a CAH. In the past, we have advised that (1) CAHs may be paid directly under the CAH payment methodology (that is, 101 percent of the reasonable costs of the CAH in accordance with sections 1814(l) and 1834(g) of the Act), or (2) CAHs could function as nonhospital settings and therefore, as such, a hospital may be paid if it incurred the costs of training occurring in the CAH as provided under section 1886(d)(5)(B)(iv) of the Act for IME and section 1886(h)(4)(E) of the Act for direct GME.

Section 5504 of the Affordable Care Act, titled ''Counting Resident Time in Non-Provider Settings,'' amended the Act in connection with ''cost reporting periods beginning on or after July 1, 2010,'' for direct GME, and for discharges on or after July 1, 2010 for IME, to permit hospitals to count the time that a resident trains in activities related to patient care in a nonprovider site in its FTE count if the hospital incurs the costs of the residents' salaries and fringe benefits for the time that the resident spends training in the nonprovider site. In connection with those periods and discharges, if more than one hospital incurs the residency training costs in a nonprovider setting, under certain circumstances, section 5504 allows each hospital to count a proportional share of the training time that a resident spends training in that setting, as determined by a written agreement between the hospitals. When Congress enacted section 5504 of the Affordable Care Act, it retained the statutory language which provides that a hospital can only count the time so spent by a resident under an approved medical residency training program in its FTE count if that *one* single hospital by itself ''incurs all, or substantially all, of the costs for the training program in that setting.'' Congress made that longstanding substantive standard and requirement applicable to ''cost reporting periods beginning before July 1, 2010'' for direct GME, and to ''discharges occurring on or after October 1, 1997, and before July 1, 2010'' for IME (Sections 1886(d)(5)(B)(iv)(I) and 1886(h)(4)(E)(i) of the Act).

Section 5504 also changed the manner in which the Act refers to sites outside the hospital in which residents train. Specifically, section 5504(a)(4), amended the Act by adding at the end of section 1886(h)(4)(E) a sentence that specifically identified such ''outpatient settings'' as ''nonprovider setting[s].'' That is, prior to the enactment of the Affordable Care Act, section 1886(h) of the Act did not include a specific term, but rather used the phrase, ''without regard to the setting'' in which the residents train, and now, with amendments from the Affordable Care Act, the Act specifically refers *both* to the phrase, ''without regard to the setting'' and to the phrase ''time spent in a nonprovider setting.'' (We invite readers to compare section 1886(h)(4)(E)(i) of the Act) as of 2010 with sections 1886(h)(4)(E)(i) and 1886(h)(4)(E)(ii) of the Act as of 2011.)

We also note that prior to the amendment in section 5504(b) of the Affordable Care Act, section 1886(d)(5)(B)(iv) of the Act relating to IME referenced training in a ''nonhospital'' setting. This remains true in the wake of the Affordable Care Act for ''discharges occurring on or after October 1, 1997 and before July 1, 2010.'' (We refer readers to section 1886(d)(5)(B)(iv)(I) of the Act.) However,

effective for ''discharges occurring on or after July 1, 2010,'' the IME statutory language refers to training in a ''nonprovider'' setting. (We refer readers to section 5504(b) of the Affordable Care Act and section 1886(d)(5)(B)(iv)(II) of the Act.)

We acknowledge that, prior to the effective date of section 5504 of the Affordable Care Act (July 1, 2010), in the preamble of rules and in other policy discussions, we have used both the term ''nonhospital'' and ''nonprovider'' interchangeably in the context of allowing a hospital to count residents training at locations outside the hospital. We amended the regulations at § 412.105(f)(1)(ii)(E) for IME and § 413.78(g) for direct GME to reflect the changes made by section 5504 of the Affordable Care Act. Section 413.78(g) is explicitly made applicable only to ''cost reporting periods beginning on or after July 1, 2010,'' whereas earlier cost reporting periods are governed by other preceding paragraphs of § 413.78.

b. Residents in Approved Medical Residency Training Programs That Train at CAHs

Section 4201 of the BBA of 1997 (Pub. L. 105–33) amended section 1820 to the Act to create facilities called ''Critical Access Hospitals'' (CAHs). Following the enactment of the BBA, but before the enactment of the Affordable Care Act, we were asked if and how CMS would pay for residents that rotate to a CAH for some portion of the residency training program when another hospital pays for the costs of the training at the CAH. To answer this question, we considered that a CAH is a unique facility that, by definition, is not always a hospital. That is, section 1861(e) of the Act states that ''the term 'hospital' does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1)).'' Because a CAH is generally not considered a ''hospital'' under section 1861(e) of the Act, we concluded that a CAH could be treated as a nonhospital site for GME purposes. If a CAH could be treated as a nonhospital site for GME purposes, we also concluded that if another hospital (such as an IPPS hospital that is subject to payment under section 1886(h) of the Act or an IPPS-excluded hospital), incurred the costs of training the FTE residents for the portion of the time that they train at the CAH, and met the requirements of the regulations at §§ 413.78(d) through (f), the hospital could claim the FTE residents training at the CAH for IME and/or direct GME purposes.

We recently determined that, as a result of the amendments made by section 5504 of the Affordable Care Act, we should reevaluate our policy regarding whether payment can be made to a hospital that incurs the costs of the FTE residents training at a CAH.

Section 1861(u) of the Act states that a ''provider of services'' is ''a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or . . . a fund.'' Therefore, while section 1861(e) of the Act states that a CAH is excluded from the definition of ''hospital'' unless the context requires otherwise, a CAH is a ''provider.''

Because section 5504(a) of the Affordable Care Act amended sections 1886(d)(5)(B)(iv)(II) and 1886(h)(4)(E) of the Act on a prospective basis to specifically identify the setting in which time spent by residents training outside of the hospital setting may be counted for both direct GME and IME purposes, a hospital's ability to count residents not training in the hospital is now limited to only those settings that are ''nonproviders.'' Although the term ''nonprovider'' is not defined in the statute, we believe it is reasonable to define the term as meaning those settings that do not meet the definition of ''provider'' at section 1861(u) of the Act.

Accordingly, because a CAH is defined as a provider in the statute, we are proposing that, effective for portions of cost reporting periods occurring on or after October 1, 2013, a hospital may not claim the time FTE residents are training at a CAH for IME and/or direct GME purposes. However, under policies that were applicable prior to October 1, 2013, and that continue to apply on and after October 1, 2013, a CAH may incur the costs of training the FTE residents for the time that the FTE residents rotate to the CAH, and receive payment based on 101 percent of its Medicare reasonable costs under § 413.70 of the regulations. We also note that, consistent with the regulations at § 413.24(d)(7), a CAH may not include as an allowable cost the portion of any training costs associated with the time that a resident is *not* training at the CAH and its provider-based facilities.

5. Expiration of Inflation Update Freeze for High Per Resident Amounts (PRAs)

The Balanced Budged Refinement Act (BBRA) of 1999 (Pub. L. 106–113) amended section 1886(h)(2) of the Act to establish a methodology for the use of a national average per resident amount (PRA) in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. The BBRA established a ''floor'' for hospital-specific PRAs at 70 percent of the locality-adjusted national average PRA. In addition, the BBRA established a ''ceiling'' that limited the annual adjustment to a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average PRA. Section 511 of the Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554) further amended section 1886(h)(2) of the Act by increasing the floor established by the BBRA to 85 percent of the locality-adjusted national average PRA, for cost reporting periods beginning in FY 2002. For purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and ceiling to determine whether the hospital-specific PRA should be revised. Section 711 of the Medicare Modernization Act of 2003 (Pub. L. 108–173) amended section 1886(h)(2)(D)(iv)(I) of the Act by freezing the annual CPI–U updates to hospital-specific PRAs for those PRAs that exceed the ceiling for FYs 2004 through 2013. The implementing regulations for these statutory provisions are located at 42 CFR 413.77(d).

We are providing notice here that the ''freeze'' for PRAs that exceed the ceiling expires beginning in FY 2014. That is, for cost reporting periods beginning on or after October 1, 2013, the usual full CPI–U update, as determined under 42 CFR 413.77(c)(1), would apply to all PRAs for direct GME payment purposes.

K. 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 7 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, which established the rural community hospital demonstration program. Sections 3123 and 10313 of the Affordable Care Act changed 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 that begins on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act requires, 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 Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation (section 410A(g)(4)(A) of Public Law 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of such Act). 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 (section 410A(g)(2) of Public Law 108–173, as added by section 3123(a) and amended by section 10313 of the Affordable Care Act). Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States under section 410A(a)(2) of Public Law 108–173 for purposes of 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 (section 410A(g)(3) of Public Law 108–173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act).

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 are 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 and that are still participating, the new selection led to a total of 23 hospitals in the demonstration.

In addition, section 410A(c)(2) of Public Law 108–173 required that, ''[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.'' This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral 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 nine IPPS final regulations, 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 2013 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, and 77 FR 53449, 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 light of the statute's budget neutrality requirement, in this FY 2014 IPPS/LTCH PPS proposed rule, we are proposing to continue to use the methodology we finalized in FY 2013 to calculate a budget neutrality adjustment factor to the FY 2014 national IPPS rates.

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 was also 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 and 2013, 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. (We note that section 410A of Public Law 108–173 was later amended by the Affordable Care Act.) 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 have 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 we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we note 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 have been 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. (For only a fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality impossible at this time for any given year.)

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 it. We noted that the revised methodology varied, in part, from that finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through 51705). Specifically, in adopting refinements to the methodology, our objective was to simplify the calculation so that it included as few steps as possible. In addition, 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. We stated that we believed this approach would maximize the precision of our calculation because it would more closely replicate payments made with and without the demonstration. 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 were making changes to certain aspects of the budget neutrality offset amount calculation for FY 2013, several core components of the methodology would

remain unchanged. For example, we continued to include in the budget neutrality offset amount methodology 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). However, finalized cost reports for the hospitals participating in the demonstration were not available for FYs 2007, 2008, 2009, and 2010 at the time of development of the FY 2013 IPPS/LTCH PPS final rule. Therefore, we were unable to finalize this component of the budget neutrality offset calculation. We stated in the final rule that we expected settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FYs 2007, 2008, 2009, and 2010) to be available prior to the FY 2014 IPPS/LTCH PPS proposed rule.

2. Proposed FY 2014 Budget Neutrality Offset Amount

For the reasons discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), we are proposing to continue to use the methodology finalized in that final rule to calculate a budget neutrality adjustment factor to be applied to the FY 2014 national IPPS payment rates. As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53451), we revised our methodology in that final rule to further improve and refine the calculation of the budget neutrality offset amount and to simplify the methodology so that it includes only a few steps. Consistent with the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, the proposed methodology for calculating the estimated FY 2014 demonstration cost for the 23 currently participating hospitals is as follows:

Step 1: For each of the 23 participating hospitals, we are proposing to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for the hospital's cost reporting period ending in CY 2011). The general reasonable cost amount calculated under the reasonable cost methodology is hereafter referred to as the ''reasonable cost amount.'' As we explained in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53451), we believe that a way to streamline our methodology for calculating the budget neutrality offset amount would be to use cost reports with the same status and from the same time period for all hospitals participating in the demonstration. Because ''as submitted'' cost reports ending in CY 2011 are the most recent available cost reports, we believe they would be an accurate predictor of the costs of the demonstration in FY 2014 because they give us a recent picture of the participating hospitals' costs.

Because section 410A of Public Law 108–173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we also are proposing to include the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, within the general total estimated FY 2011 reasonable cost amount for covered inpatient hospital services under the demonstration. As indicated above, we are proposing to use ''as submitted'' cost reports for the hospital's cost reporting period ending in CY 2011 for this calculation.

We are proposing to sum the two above-referenced amounts to calculate the general total estimated FY 2011 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to multiply this sum (that is, the general total estimated FY 2011 reasonable cost amount for covered inpatient hospital services for all 23 hospitals) by the FYs 2012, 2013, and FY 2014 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. In this proposed rule, we have used the current estimate of the FY 2014 IPPS market basket percentage increase provided by the CMS Office of the Actuary. We are proposing to use the final IPPS market basket increase in the final rule. We also are proposing to then multiply the product of the general total estimated FY 2011 reasonable cost amount for all 23 hospitals and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for the years 2012 through 2014—the result would be the general total estimated FY 2014 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to apply the IPPS market basket percentage increases applicable for FYs 2012 through 2014 to the FY 2011 reasonable cost amount described above to model the estimated FY 2014 reasonable cost amount under the demonstration. We are proposing 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 for the years involved. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and is proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledge the possibility that inpatient caseloads for small hospitals may fluctuate, and are proposing 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 23 hospitals, we are proposing to identify the general estimated amount that would otherwise be paid in FY 2011 under applicable Medicare payment methodologies for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2011) if the demonstration was not implemented. Similarly, as in Step 1, for the hospitals that provide swing-bed services, we are proposing to identify the estimated amount that generally would otherwise be paid for these services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2011) and include it in the total FY 2011 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration. We are proposing to sum these two amounts in order to calculate the estimated FY 2011 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration.

We are proposing to multiply the above amount (that is, the estimated FY 2011 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration) by the FYs 2012 through 2014 IPPS applicable percentage increases. In this proposed rule, the current estimate of the applicable percentage increase is specified in section V.A.1. of this preamble. This methodology differs from Step 1, in which we are proposing to apply the market basket percentage increases to the sum of the hospitals' general total FY 2011 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would

constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates. Hospitals participating in the demonstration would be participating under the IPPS payment methodology if they were not in the demonstration. Then we are proposing to multiply the product of the estimated FY 2011 total payments that generally would otherwise be made without the demonstration and the IPPS applicable percentage increases applicable to the years involved by a 3-percent annual volume adjustment for FYs 2012 through 2014. The result would be the general total estimated FY 2014 costs that would otherwise be paid without the demonstration for covered inpatient hospital services to the 23 participating hospitals.

Step 3: We are proposing to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the 23 hospitals for covered inpatient hospital services for FY 2014 if the demonstration was not 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 23 hospitals for covered inpatient hospital services for FY 2014). We are proposing that the resulting difference would be the amount for which an adjustment to the national IPPS rates would be calculated.

For this proposed rule, the resulting difference is $46,515,865. For this FY 2014 IPPS/LTCH PPS proposed rule, this amount is the estimated amount for which an adjustment to the national IPPS rates is being calculated. This estimated amount is based on the specific assumptions identified regarding the data sources that are used, that is, ''as submitted'' recently available cost reports. We note that if updated data become available prior to the FY 2014 final rule, we are proposing to use them to the extent appropriate to estimate the costs of the demonstration program in FY 2014. Therefore, this estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

Similar to previous years, we are proposing 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) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. Because of delays affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we are unable to determine at this time the specific 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. (For only a fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality offset impossible at this time for any given year.) Similar to previous years, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2007, 2008, 2009, or 2010) are available prior to the FY 2014 IPPS/LTCH PPS final rule, we will include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. (The final settled costs of the demonstration for a year would be calculated by subtracting the total amount that would otherwise be paid under the applicable Medicare payment systems without the demonstration for the year from the amount paid to those hospitals under the reasonable cost methodology for such year.)

L. Hospital Emergency Services Under EMTALA: Technical Change (§ 489.24(f))

In a final rule issued in the **Federal Register** on May 16, 2012 (77 FR 29002 through 29031), we made changes to a number of regulations under 42 CFR Chapter IV governing the Medicare and Medicaid programs to achieve regulatory reforms under Executive Order 13563 on Improving Regulation and Regulatory Review and the Department's Plan for Retrospective Review of Existing rules. In the May 16, 2012 final rule (77 FR 29021), we stated that, in response to comments from the public recommending that we discontinue our use of the term ''recipient'' under Medicaid, we made a nomenclature change to replace ''recipient'' with ''beneficiary'' throughout 42 CFR Chapter IV in order to conform our regulations to our current use of the term ''beneficiary.'' Our current use of the term ''beneficiary'' means all individuals who are entitled to, or eligible for, Medicare or Medicaid services. However, we inadvertently replaced ''recipient'' with ''beneficiary'' in the title of the regulations at 42 CFR 489.24(f), which now reads ''Beneficiary hospital responsibilities.'' The regulations at 42 CFR 489.24(f) specifically discuss the responsibilities of a hospital with specialized capabilities to accept the appropriate transfer of an individual as required by the Emergency Medical Treatment and Labor Act. The use of the word ''recipient'' in the title of 42 CFR 489.24(f) is appropriate because the regulations are discussing the requirements of the ''receiving'' hospital. The term ''recipient'' in this context is not referring to a Medicare or Medicaid patient, but rather to the hospital. Therefore, in this proposed rule, we are proposing to replace the word ''beneficiary'' with the word ''recipient'' so that the section heading of paragraph (f) of 42 CFR 489.24 is corrected to read as it did prior to the nomenclature change. The corrected regulation text at 42 CFR 489.24(f) would read ''Recipient hospital responsibilities.''

M. Hospital Services Furnished Under Arrangements

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we included a provision that limits the circumstances under which a hospital may furnish services to Medicare beneficiaries ''under arrangement.'' Under the revised policy, therapeutic and diagnostic services are the only services that may be furnished under arrangements outside of the hospital to Medicare beneficiaries. ''Routine services'' (that is, bed, board, and nursing and other related services) must be furnished in the hospital. Under this revised policy, routine services furnished to Medicare beneficiaries as inpatients in the hospital are considered services furnished by the hospital. If these services are furnished outside of the hospital, the services are considered to be furnished ''under arrangement.'' As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53453 through 53454), we have become aware that a number of hospitals affected by this policy need additional time to restructure existing arrangements and establish necessary operational protocols to comply with the requirement that therapeutic and diagnostic services are the only services that may be furnished outside of the

hospital to Medicare beneficiaries ''under arrangement,'' and that ''routine services'' must be furnished in the hospital.

In the FY 2013 IPPS/LTCH PPS final rule, we stated that while we believe the policy to be correct and consistent with the statutory language, because a number of hospitals were actively pursuing compliance that involved building construction or restructuring, we postponed the effective date of the requirement to give hospitals additional time to comply with the provision. In the FY 2013 IPPS/LTCH PPS final rule, we changed the implementation date of the requirement to be effective for cost reporting periods beginning on or after October 1, 2013. We stated that we expected that, during FY 2013, hospitals would have completed the work needed to ensure compliance with the requirement.

While we still believe that our policy is correct and consistent with the statutory language, we are aware that a number of hospitals are still actively pursuing compliance with the requirement through major building construction to be completed in 2014. Therefore, we believe it is appropriate to further postpone the effective date of this requirement to give those hospitals additional time to comply. In this proposed rule, we are proposing to change the implementation date of the requirement to be effective for services provided on or after January 1, 2015 (instead of effective with cost reporting periods beginning on or after October 1, 2013). Because there are hospitals in the midst of significant building projects that, when completed, will enable the hospital to provide routine services in compliance with the requirements of this revised policy, we believe it is appropriate to further delay the effective date. We expect that, with the additional time before the revised ''under arrangement'' policy becomes effective, hospitals will complete the work needed to ensure compliance with the new requirement. Effective for services provided on or after January 1, 2015, all hospitals would need to be in full compliance with the revised policy for services furnished under arrangement. We will continue to work with affected hospitals to communicate the requirement established by this provision, and to provide continued guidance regarding compliance with the provision.

N. Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A

In this section of the proposed rule, we are clarifying what is required for Medicare Part A payment of hospital inpatient services. In addition, we are proposing a time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay, as part of our medical review criteria for payment of hospital inpatient services under Part A.

1. Background

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. We also solicited and summarized public comments on potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admissions decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to a hospital as an inpatient. (In this section, ''hospital'' means hospital as defined at section 1861(e) of the Act, but includes critical access hospitals (CAHs) unless otherwise specified. Although the term ''hospital'' does not generally include CAHs, section 1861(e) of the Act provides that the term ''hospital'' includes CAHs if the context otherwise requires. We believe it is appropriate to propose to apply our proposed policies to CAHs as well as other hospitals.) Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment before a decision can be made regarding whether a patient will require further treatment as a hospital inpatient or if he or she is able to be discharged from the hospital (Section 20.6, Chapter 6 of the Medicare Benefit Policy Manual (MBPM) (Pub. 100–02)).

In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 8 percent in 2011. This trend concerns us because of the potential financial impact on Medicare beneficiaries, and we have published educational materials for beneficiaries to inform them of their respective liabilities as a hospital outpatient or inpatient.[58] Beneficiaries who are treated for extended periods of time as hospital outpatients receiving observation services may incur greater financial liability than they would if they were admitted as hospital inpatients. They may incur financial liability for Medicare Part B copayments; the cost of self-administered drugs that are not covered under Part B, and the cost of post-hospital SNF care because section 1861(i) of the Act requires a prior 3-day hospital inpatient stay for coverage of post-hospital SNF care under Medicare Part A. In contrast, as a hospital inpatient under Medicare Part A, a beneficiary pays a one-time deductible for all hospital inpatient services provided during the first 60 days in the hospital of the benefit period. Therefore, an inpatient deductible does not necessarily apply to all hospitalizations. Medicare Part A coinsurance applies after the 60th day in the hospital.

In the CY 2013 OPPS/ASC proposed rule and final rule with comment period (77 FR 45155 and 77 FR 68426, respectively) and in a proposed rule entitled, ''Medicare Program; Part B Inpatient Billing in Hospitals'' that went on display at the Office of the Federal Register on March 13, 2013, and was issued in the **Federal Register** on March 18, 2013 (78 FR 16632) (''Part B Inpatient Billing proposed rule''), we discussed how the trend towards the provision of extended observation services may be attributable in part to hospitals' concerns about Medicare's payment policy for billing under Part B when a Part A hospital inpatient claim is denied because a Medicare review contractor determines that the inpatient admission was not reasonable and necessary under section 1862(a)(1)(A) of the Act. Under longstanding Medicare policy, in these situations, hospitals could only receive payment for a limited set of largely ancillary inpatient services under Part B. We stated that we have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for long periods of time, rather than admitting them as inpatients.

[58] CMS Pamphlets: ''Are You a Hospital Inpatient or Outpatient? If You Have Medicare Ask!'', CMS Product No. 11435, Revised, February 2011; ''How Medicare Covers Self Administered Drugs Given in Hospital Outpatient Settings,'' CMS Product No. 11333, Revised, February 2011.

As a step to address this issue, in the Part B Inpatient Billing proposed rule (78 FR 16632), we proposed to revise our Part B inpatient billing policy to allow payment for all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient. Specifically, we proposed that when a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was deemed not to be reasonable and necessary, or when a hospital determines under § 482.30(d) or § 485.641 of the regulations after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary, a hospital may be paid for all Medicare Part B services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient, if the beneficiary is enrolled in Medicare Part B. This policy would apply when CMS or a Medicare review contractor determines that the hospital admission was not reasonable and necessary or when a hospital determines after a beneficiary has been discharged that the beneficiary should have received hospital outpatient services rather than hospital inpatient services. We also proposed to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service.

In addition to evaluating our policy related to Medicare Part B inpatient billing following denials of Medicare Part A inpatient claims on the basis that the inpatient admission was not reasonable and necessary or following a hospital self-audit, we also believe it is important to consider whether we can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68426 through 68433), we discussed revising hospital inpatient status criteria as one of several policy clarifications or changes suggested by stakeholders to improve our policies governing when a Medicare beneficiary should be admitted as an inpatient, and how hospitals should be paid by Medicare for the associated costs they incur.

Specifically, stakeholders suggested that we redefine ''inpatient'' using parameters other than the current requirements of medical necessity and a physician order, such as using the beneficiary's length of stay at the hospital. Currently, a beneficiary's length of stay may be a factor in determining whether he or she should be admitted as an inpatient to the hospital, but it is not the only factor for this determination. Our current manual instructions state that, typically, the decision to admit a beneficiary as an inpatient should be made within 24 to 48 hours of observation care, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (MBPM)). We state that physicians should use a 24-hour period as a benchmark, that is, they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. We state that, generally, a beneficiary is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will remain at least overnight, whether or not the beneficiary is later discharged or transferred and is not present overnight. Nevertheless, our longstanding policy consistently has been that we do not define or pay under Medicare Part A for inpatient admissions solely on the basis of the length of time the beneficiary actually spends in the hospital. Rather, we rely on the physician to use his or her clinical judgment and evaluation of the patient's needs to make the determination. We have stated in our manual guidance that the inpatient admission decision is a complex medical judgment that should take into consideration many factors, such as the patient's medical history and medical needs, the types of facilities available to inpatients and outpatients, the hospital's bylaws and admission policies, the relative appropriateness of treatment in each setting, patient risk of an adverse event, and other factors described in the MBPM provisions. The physician or other practitioner responsible for a patient's care at the hospital also is responsible for deciding whether the patient should be admitted as an inpatient.

We believe that our current inpatient admission criteria are valid and appropriately reflect that the decision to admit a patient as a hospital inpatient is a complex medical judgment that can be made only after the physician has considered a number of factors. However, upon evaluating the suggestions of stakeholders who requested that we provide more clarity in the definition of ''inpatient'' using parameters other than those that we currently use, we recognize that it would be helpful to address what the requirements are for Medicare Part A payment and when a beneficiary should be admitted as a hospital inpatient. Toward that end, in this proposed rule, we are clarifying that a beneficiary becomes a hospital inpatient if formally admitted following a physician order for hospital inpatient admission, and also are clarifying when we believe hospital inpatient admissions are reasonable and necessary based on how long beneficiaries have spent, or are reasonably expected to spend, in the hospital.

Specifically, in sections V.N.2.a. and b. of the preamble of this proposed rule, we are clarifying that a beneficiary becomes a hospital inpatient if a physician (or other qualified practitioner as provided in the regulations) orders inpatient admission in accordance with the hospital conditions of participation (CoPs), and that Medicare pays under Part A for such an admission if the order is documented in the medical record. However, as we discuss in section V.N.3.d.(1) of the preamble of this proposed rule and as we specify under proposed 42 CFR 412.46(b), the order must be supported by objective medical information for purposes of the Part A payment determinations. During Medicare contractor review of an inpatient admission, documentation in the medical record is evaluated in conjunction with the physician order and the physician certification that is also required for payment of hospital inpatient services under section 1814(a) of the Act and 42 CFR 424.13. In section V.N.2. of the preamble of this proposed rule, we describe the requirements for the physician order. In section V.N.3. of the preamble of this proposed rule, we discuss the role of the physician certification in medical review where applicable.

In addition, in section V.N.3. of the preamble of this proposed rule, we are proposing a new benchmark for purposes of medical review of hospital inpatient admissions, based on how long the beneficiary is in the hospital. Under our proposal, Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services. If a hospital is found to be abusing this 2-midnight presumption for nonmedically necessary inpatient hospital admissions and payment (in other words, the

hospital is systematically delaying the provision of care to surpass the 2-midnight timeframe), CMS review contractors would disregard the 2-midnight presumption when conducting review of that hospital. Similarly, we would presume that hospital services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear documentation in the medical record supporting the physician's order and expectation that the beneficiary would require care spanning more than 2 midnights or the beneficiary is receiving a service or procedure designated by CMS as inpatient-only. We note that our current manual instructions referenced above, indicating that physicians should use a 24-hour period and the expectation of a beneficiary's need for an overnight stay in the hospital as inpatient admission benchmarks, remain in effect until we have finalized a new policy, at which time we will consider whether and how the existing instructions should be updated.

2. Requirements for Physician Orders

The requirements for physician and other qualified practitioner orders are contained under the hospital and CAH CoPs (42 CFR Parts 482 and 485), which are the patient health and safety standards with which all Medicare and Medicaid hospitals and CAHs must comply in order to participate in the Medicare and Medicaid programs. The CoPs apply to facilities and services provided to all hospital patients, not just Medicare or Medicaid patients. The hospital medical record services CoP at § 482.24(c) specifies that a patient's medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. The hospital medical record services CoP also requires specific elements that must be included in the patient record; among these elements are an ''admitting diagnosis'' and ''all practitioners' orders.'' The CAH CoP at § 485.638 contains similar, although not identical, language. In addition, under the hospital CoP at § 482.12(c)(2), patients are admitted to the hospital as inpatients only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital. Under the hospital CoP at § 482.12(c)(1), every Medicare patient must be under the care of a physician or other type of practitioner listed in the regulations (''the practitioner responsible for the care of the patient''). Although the CoPs do not distinguish the term ''inpatient admission order'' from the required physician or practitioner orders in the regulatory text, it is an accepted standard of practice in hospitals and CAHs that such an order must be given before a patient can be admitted to a hospital or CAH. Similarly, the requirement that a patient is admitted as an inpatient ''only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital'' is understood to mean that a patient is admitted by way of an inpatient admission order given by the practitioner responsible for the care of the patient, provided that the practitioner, either a physician or other licensed practitioner, has been authorized by the State and granted such privileges by the hospital to do so.

We note that, under these requirements of the CoPs, patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by his or her State to admit patients to a hospital. In addition, § 482.12(c)(2) of the regulations requires that a Medicare patient who is admitted by a practitioner not specified in paragraph (c)(1) of this same section of the CoPs must then be under the care of a doctor of medicine or osteopathy; however, this ''. . . is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.'' Therefore, the CoPs do not specifically prohibit the delegation of an inpatient admission to a nonphysician practitioner; however, neither do they specifically authorize it. We have stated that for payment purposes, as provided in the COPs at § 482.12(c), the physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient (Section 1, Chapter 10 of the MBPM). In specifying that the practitioner responsible for the patient's care is responsible for making the admission decision, we precluded that practitioner from delegating the decision to another individual. Therefore, while the COPs do not preclude a doctor of medicine or osteopathy from delegating authority to other individuals, we are specifically clarifying in regulation that, for payment purposes, the authority to admit cannot be delegated to an individual who lacks that authority in his or her own right.

The CoPs also allow for inpatient admission orders to be given verbally in person or over the telephone as well as through the use of preprinted and electronic standing orders, order sets, and protocols. Such inpatient admission orders must be in accordance with the requirements for orders found at § 482.23(c)(3)(i) and (ii), and at § 482.24(c)(2) and (3) of the regulations. Included in these provisions is the requirement that if verbal orders are used, they must be used infrequently. In addition, *all* orders must be authenticated promptly by the ordering practitioner or another practitioner responsible for the care of the patient. While the CoPs do allow for inpatient admission orders through these mechanisms, it must be stressed that the CoPs also require that the patient medical record contains documentation that supports the decision reflected in the physician order to admit the patient to the hospital.

For all patients (not just Medicare beneficiaries), the physician admission order is the most basic means by which the hospital inpatient stay begins and by which the course of treatment and care is initially guided. The order details not only who is responsible for the patient's care while in the hospital, but also directs that care through the various diagnostic, dietary, medication, and other treatment orders. Before a Medicare beneficiary or any patient can be treated, there must be physician orders (including, and perhaps most importantly, the initiating admission order) to guide that treatment. Therefore, under the CoPs, the practitioner responsible for the care of the patient must determine that inpatient admission is medically necessary and order both the admission and reasonable and necessary inpatient services.

While the requirement for the physician admission order has long been clear in the CoPs, we are proposing to state explicitly in our payment regulations that admission pursuant to this order is the means whereby a beneficiary becomes a hospital inpatient and, therefore, is required for payment of hospital inpatient services under Medicare Part A. Accordingly, we are proposing to add a new § 412.3 titled ''Admissions,'' that would define a hospital inpatient admission as follows: ''(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with paragraph (b) of this section [discussed below] and §§ 482.24(c),

482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital.'' This physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.

In proposed new § 412.3(b), we would clarify that, in contrast to the CoPs, for payment under Part A, the hospital inpatient admission order must be furnished by a physician or other specified practitioner as follows: ''(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is responsible for the inpatient care of the patient at the hospital. The practitioner may not delegate the decision (order) to another individual who is not responsible for the care of that patient, is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.''

3. Proposed Inpatient Admission Guidelines

a. Background

CMS is authorized under section 1893 of the Act to implement the Medicare Integrity Program to conduct medical review of claims and ensure appropriateness of Medicare payment. Medicare review contractors, such as Medicare Administrative Contractors (MACs), Recovery Auditors (formerly known as the Recovery Audit Contractors, or RACs), the Comprehensive Error Rate Testing (CERT) Contractor, and other review contractors are hired by CMS to review claims on a pre-payment or post-payment basis to determine whether a claim should be paid or denied or whether a payment was properly made under Medicare payment rules. Following documentation reviews, many claim denials are made or improper payments identified because either—

- The claim was incorrectly coded (for example, the provider did not appropriately assign the individual or grouper inpatient and/or outpatient coding for the care documented); or
- The services were not medically necessary (that is, the review indicates that the services billed were not reasonable and necessary based upon Medicare payment policies or that the documentation was insufficient to support the medical necessity of the services billed).

Hospital claim errors are identified more frequently for shorter lengths of stay. The majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis).

CMS developed the CERT program to calculate the Medicare FFS program improper payment rate. The CERT program considers any claim that was paid when it should have been denied or paid at another amount (including both overpayments and underpayments) to be an improper payment. In 2012, the CERT contractor found that Medicare Part A inpatient hospital admissions for 1-day stays or less had an improper payment rate of 36.1 percent. The improper payment rate decreased significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. The improper payment rate further decreased to 8 percent for those beneficiaries who were treated as hospital inpatients for 4 days.

Inpatient hospital short-stay claim errors are frequently related to minor surgical procedures or diagnostic tests. In such situations, the beneficiary is typically admitted as a hospital inpatient after the procedure is completed on an outpatient basis, monitored overnight as an inpatient, and discharged from the hospital in the morning. Medicare review contractors typically find that while the underlying services provided were reasonable and necessary, the inpatient hospitalization following the procedure was not (that is, the services following the procedure should have been provided on an outpatient basis).

Through this proposed rule, we are seeking to clarify our longstanding policy on how Medicare review contractors review inpatient hospital admissions for payment under Medicare Part A. We also will issue revised guidance to physicians and hospitals regarding when a hospital inpatient admission should be ordered for Medicare beneficiaries once this proposed rule is finalized.

b. Correct Coding Reviews

We are not proposing any changes to coding review strategies for hospital claims. Reviewers will continue to ensure that the correct codes were applied and are supported by the medical record documentation.

c. Complete and Accurate Documentation

When conducting complex medical review, Medicare review contractors will continue to employ clinicians to review practitioner documented procedures and ensure that they are supported by the submitted medical record documentation. Such is the case when complex medical review is performed currently and will continue to be the case when the proposed review criteria are implemented.

d. Medical Necessity Reviews

(1) Physician Order and Certification

In statute and regulation, Medicare has certain requirements for physician orders and certifications, discussed above, that must be satisfied before payment may be made under Part A. We are proposing to codify in 42 CFR 412.46(b) the longstanding requirement that medical documentation must support the physician's order and certification, as prescribed by CMS Ruling 93–1. The proposed new paragraph (b) titled ''Physician's order and certification regarding medical necessity'' would read, ''No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of this chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order and certification will be evaluated in the context of the evidence in the medical record.'' We are not proposing any changes to our current requirements for practitioner documentation of services ordered and furnished. While the physician order and the physician certification are required for all inpatient hospital admissions in order for payment to be made under Part A, the physician order and the physician certification are not considered by CMS to be conclusive evidence that an inpatient hospital admission or service was medically necessary. Rather, the physician order and physician certification are considered along with other documentation in the medical record. CMS and its medical review contractors base their payment determinations on objective medical information documented in the medical record about the patient's condition and the services received. This documentation will be reviewed from the claims form and, when necessary, the medical record containing the physician order, the physician certification, and other supporting documentation that are required for payment under Medicare Part A.

(2) Medical Review Criteria for All Hospital Services

We will continue to review individual claims to ensure the hospital services furnished to beneficiaries are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,'' as required by section 1862(a)(1) of the Act. Any hospital service determined to be not reasonable or necessary may not be paid under Medicare Part A or Part B.

(3) Inpatient Hospital Admission Guidelines

In this proposed rule, we are proposing inpatient hospital admission guidance under which a physician or other practitioner should order admission if he or she expects that the beneficiary's length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only under 42 CFR 419.22. We are proposing that the starting point for this time-based instruction would be when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided. However, we are soliciting public comments on this proposed method of calculating the length of stay for purposes of this 2-midnight threshold proposal.

There are certain types of cases for which a hospital inpatient admission is rarely appropriate. We have stated in our existing Medicare manual that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24), the services should be provided as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). We note that there has been considerable variation in the interpretation of this instruction. Therefore, we are proposing to clarify this policy and codify our general rule at § 412.3(c)(1), that in addition to services designated by CMS as inpatient only, surgical procedures, disgnostic tests, and other treatments would be generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A. This would be the case regardless of the hour that the patient came to the hospital or whether the patient used a bed.

Under our proposed policy, the judgment of the physician and the physician's order for inpatient admission should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In accordance with current policy, factors that may result in an inconvenience to a beneficiary or family would not, by themselves, justify inpatient hospital admission. When such convenience factors affect the beneficiary's health, CMS and/or its contractor would consider these factors in determining whether inpatient hospital admission was appropriate. The factors that lead a physician to admit a particular patient based on the physician's clinical expectation are significant clinical considerations.

In accordance with current policy and as discussed above, the physician would be required to clearly and completely document the clinical facts supporting the inpatient hospital admission. It is the documentation of the reasonable basis for the expectation of a stay crossing 2 midnights that would justify the medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay and whether it ultimately crosses 2 midnights. As a result of the relationship that develops between a physician and his or her patient, the physician is in a unique position to incorporate complete medical evidence in beneficiary's medical records, including his or her opinions and the pertinent medical history of the patient. In creating the medical assessment, medical history, and discharge notes that become part of the medical record, we believe the physician has ample opportunity to explain in detail why the course of treatment was appropriate in the context of that patient's acute condition. In addition, the physician has the opportunity to describe and explain aspects of the beneficiary's medical history that may not otherwise be apparent. Therefore, the physician would be responsible for ensuring that the beneficiary's medical record includes complete medical information, and this information would be the basis for determining the medical necessity of the prescribed treatment. The final determination by the Medicare review contractor for payment purposes would not be based solely on the physician's order and certification, and would reflect equal weight and evaluation of all documentation contained in the medical record.

We acknowledge that there may be an unforeseen circumstance that results in a shorter beneficiary stay than the physician's expectation of 2 midnights. We expect that the majority of such inpatient hospital admissions would occur when an inpatient hospital admission is appropriately ordered, but a beneficiary's transfer or death interrupts the beneficiary's hospital stay that would have otherwise spanned 2 midnights. Therefore, we provide an exception to the general rule in proposed § 412.3(c)(2), that ''If an unforeseen circumstance, such as beneficiary death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and the hospital inpatient payment may be made under Medicare Part A.'' Documentation of such a circumstance constitutes supporting medical documentation in determining whether the inpatient hospital admission is reasonable and necessary for Medicare Part A payment. In addition, the physician must certify that inpatient hospital services were medically necessary in accordance with section 1814(a) of the Act and 42 CFR Part 424, Subpart B.

(4) Medical Review Criteria for Payment of Inpatient Hospital Admissions Under Part A

Until such time as this proposed rule is finalized, Medicare review contractors will continue to follow the current CMS policy and instruction regarding medical review criteria for payment of inpatient admissions under Medicare Part A.

Under our proposed medical review policy, Medicare's external review contractors would presume that hospital inpatient status is reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined as encounters crossing 2 midnights) after admission. Medical review efforts for inpatient hospital admissions greater than 2 midnights would focus on undue delays in the provision of care in an attempt to meet the 2-midnight threshold (that is, inpatient hospital admissions where medically necessary treatment was not

provided on a continuous basis throughout the hospital stay and the services could have been furnished in a shorter timeframe). Beneficiaries should not be held in the hospital absent medically necessary care for the purpose of meeting the 2-midnight presumption.

Patient status reviews for those admissions with lengths of stay greater than 2 midnights would typically be conducted if CMS suspects that a provider is using the time-based presumption to effectuate systematic abuse or gaming. Review contractors would continue to assess claims in which the beneficiary span of care crossed the 2-midnight threshold:

- To ensure the services provided were medically necessary;
- To validate provider coding and documentation as reflective of the medical evidence;
- If the CERT Contractor is directed to do so under the Improper Payments Elimination and Recovery Improvement Act of 2012 (Pub. L. 112–248); or
- If directed by CMS or other authoritative governmental entity (including but not limited to the HHS Office of Inspector General and Government Accountability Office).

As a result of the proposed admission guidelines above, we are proposing that medical review efforts will focus on those inpatient hospital admissions with lengths of stay crossing only only 1midnight or less (that is, only 1 Medicare utilization day, as defined in 42 CFR 409.61 and implemented in the Medicare Benefit Policy Manual, Chapter 3, Section 20.1). As we noted earlier, such claims have traditionally demonstrated the largest proportion of inpatient hospital improper payments under Medicare Part A. If the physician admits the beneficiary as an inpatient but the beneficiary is in the hospital for less than 2 midnights after admission, we are proposing that CMS and its medical review contractors would review the inpatient admission in accordance with current policy for Part A payment, as clarified below, and would not presume that the inpatient hospital admission was reasonable and necessary for payment purposes. Medicare review contractors would evaluate the physician order for inpatient admission to the hospital, the medical documentation supporting that order, and the physician certification in order to determine whether payment under Part A is appropriate.

The Medicare review contractors would consider, in their review of the medical record, complex medical factors that support a reasonable expectation of the needed duration of the stay relative to the 2-midnight threshold. These factors include such things as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In other words, if it was reasonable for the physician to expect the beneficiary to require a stay lasting 2 midnights, even though that did not transpire, payment would be made under Medicare Part A if the documentation in the medical record reflected such complex medical factors (and the physician's order and certification requirements also are met). As discussed above, payment may be made in the case of services on Medicare's inpatient only list and in exceptional cases such as beneficiary death or transfer.

4. Proposed Payment Adjustment

The accurate determination of a beneficiary's patient status is an issue of concern across hospitals. As we discuss in section V.N.1. of the preamble of this proposed rule, in the CY 2013 OPPS/ASC proposed rule, we sought comment on actions that we could potentially undertake to address stakeholders' concerns. We received approximately 350 public comments on this issue in response to our solicitation from hospitals and hospital associations, physician associations, rehabilitative and long-term care facilities, beneficiaries, beneficiary advocacy organizations, Quality Improvement Organizations (QIOs), organizations specializing in medical necessity review, and other interested parties. In particular, as stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68429) and discussed further in section V.N.1. of the preamble of this proposed rule, we heard from some stakeholders who specifically suggested a need for us to clarify our current instructions regarding the circumstances under which Medicare will pay for a hospital inpatient admission in order to improve hospitals' ability to make appropriate admission decisions.

The issue also has a substantial impact on improper payments under Medicare Part A for short-stay inpatient hospital claims. As discussed earlier, the majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis.) In 2012, the CERT contractor found that inpatient hospital admissions for 1-day stays or less had a Part A improper payment rate of 36.1 percent. The improper payment rate decreases significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. We believe the magnitude of these national figures demonstrates that the appropriate determination of a beneficiary's patient status is a systemic and widespread issue and is not isolated to a few hospitals. We also note that the RAs have recovered more than $1.6 billion in improper payments because of inappropriate beneficiary patient status.

Our actuaries have estimated that our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services, as discussed in section V.N.3. of the preamble of this proposed rule, would increase IPPS expenditures by approximately $220 million. These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. Specifically, our actuaries examined FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters. These estimated shifts of 400,000 encounters from outpatient to inpatient and 360,000 encounters from inpatient to outpatient represent a significant portion of the approximately 11 million encounters paid under the IPPS. The net shift of 40,000 encounters represents an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters paid under the IPPS. Since shorter stay hospital inpatient encounters currently represent approximately 17 percent of the IPPS expenditures, our actuaries estimated that 17 percent of IPPS expenditures would increase by 1.2 percent under our proposed policy. These additional expenditures are partially offset by reduced expenditures from the shift of shorter stay hospital inpatient encounters to hospital outpatient encounters. Our actuaries estimated that

on average the per encounter payments for these hospital outpatient encounters would be approximately 30 percent of the per encounter payments for the hospital inpatient encounters.

In light of the widespread impact of the proposed policy discussed in section V.N.3. of the preamble of this proposed rule on the IPPS and the systemic nature of the issue as demonstrated above, we believe it is appropriate to propose to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the estimated $220 million in additional IPPS expenditures associated with this proposed policy. This special exceptions and adjustment authority authorizes us to provide ''for such other exceptions and adjustments to [IPPS] payment amounts . . . as the Secretary deems appropriate.'' We are proposing to reduce the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount by 0.2 percent.

VI. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services ''in accordance with a prospective payment system established by the Secretary.'' Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. 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. Other Proposed Changes for FY 2014—Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A

In the Medicare Part B Inpatient Billing in Hospitals proposed rule that went on display at the Office of the Fedreal Register on March 13, 2013, and that appeared in the **Federal Register** on March 18, 2013 (78 FR 16632), we proposed to revise our Part B inpatient billing policy to allow payment of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient, except for those services specifically requiring an outpatient status. This policy would apply when CMS or a Medicare review contractor determines that the hospital admission was not reasonable and necessary or when a hospital determines after a beneficiary has been discharged that the beneficiary should have received hospital outpatient services rather than hospital inpatient services. We also proposed to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service. As we discuss in section V.N. of the preamble of this proposed rule, in addition to evaluating our policy related to Medicare Part B inpatient billing following denials of Medicare Part A

inpatient claims on the basis that the inpatient admission was not reasonable and necessary or following a hospital self-audit, we also believe it is important to consider whether we can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment. Toward that end, we are presenting a proposal that would clarify that a beneficiary becomes a hospital inpatient when formally admitted following the physician order for hospital inpatient admission, and would also clarify when we believe hospital inpatient admissions are reasonable and necessary based on how long beneficiaries have spent, or are reasonably expected to spend, in the hospital as inpatients. Under this proposal, Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than one Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services. Similarly, we would presume that generally services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required inpatient care. (For a complete discussion on our proposed inpatient admission guidelines, including our proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for payment of hospital inpatient services under Medicare Part A, we refer readers to section V.N.3 of the preamble of this proposed rule.)

Our actuaries project an increase in IPPS expenditures as a result of our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services as discussed in section V.N.3. of the preamble of this proposed rule (and as briefly summarized above). These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. In making this projection, the actuaries analyzed Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters, and estimated the number of encounters that are expected to shift from outpatient to inpatient and vice versa (that is, the number that are expected to shift from inpatient to outpatient). These estimated shifts of encounters represent a significant portion of the total encounters paid under the IPPS. Our actuaries estimate that this projected net increase in inpatient encounters would increase IPPS expenditures by approximately $220 million. In light of the widespread impact on the IPPS of our proposed policy and the systemic nature of the issue, we believe it is appropriate to propose to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the estimated $220 million in additional IPPS expenditures associated with this proposed policy by proposing to apply a −0.2 percent adjustment to the operating IPPS standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount. (For additional information on our actuarial estimate, we refer readers to section V.N.5. of the preamble of this proposed rule.)

Consistent with the proposal that we are making for the operating national and Puerto Rico-specific standardized amounts and the hospital specific-rates, we believe that it is also appropriate, under the Secretary's broad authority under section 1886(g) of the Act, to propose to reduce the national capital Federal rate and Puerto Rico-specific capital rate by 0.2 percent (an adjustment factor of 0.998) to offset the estimated increase in capital IPPS expenditures associated with the projected increase in inpatient encounters that is expected to result from our proposed inpatient admission guidelines. Because hospitals receive an operating IPPS payment and also a capital IPPS payment for each discharge, we believe it would be appropriate to reduce payments under both the operating and capital IPPS to fully offset the projected increase in expenditures associated with these inpatient discharges. (We refer readers to section V.N. of the preamble of this proposed rule for a complete discussion of our policy proposal on inpatient admission guidelines, including our proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for hospital inpatient services under Medicare Part A.)

D. Proposed Annual Update for FY 2014

The proposed annual update to the capital PPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2014 is discussed in section III. of the Addendum to this proposed rule.

We note that, in section II.D. of the preamble of this proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as our proposed recoupment adjustment to the standardized amounts under section 1886(d) of the Act for FY 2014 pursuant to the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 631 of the ATRA.

Additional prospective adjustments for the MS–DRG documentation and coding effect through FY 2010 authorized under section 1886(d)(3)(A)(vi) of the Act are discussed in section II.D.7. of this preamble. Based on an analysis of FY 2010 data on claims paid through December 2011 using our historical claims-based methodology, we determined an additional prospective documentation and coding effect of +0.8 through FY 2010. Consistent with our proposal for the operating IPPS standardized amounts, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27997), we proposed to reduce the national capital Federal rate in FY 2013 by an additional 0.8 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system that did not reflect an increase in case-mix severity through FY 2010. Numerous commenters objected to that proposal, and many commenters continued to assert that our estimates of documentation and coding were overstated, and could be explained by other factors. These commenters also focused on part of the analysis provided by MedPAC in its FY 2012 comment letter indicating that a slightly smaller additional prospective adjustment of −0.55 percent rather than −0.8 percent might be required to offset the cumulative MS–DRG documentation and coding effect through FY 2010. (77 FR 53278 through 53280) Many commenters requested that if CMS were to apply an additional prospective adjustment for the MS–DRG documentation and coding effect through FY 2010, it should subtract 0.25 percentage points from its estimate, for an adjustment of −0.55 percent, given the MedPAC analysis. After consideration of the public comments, we recognized that the issue of the

estimate used for the cumulative MS–DRG documentation and coding effect through FY 2010 may merit further consideration. Therefore, consistent with the policy we adopted for the operating IPPS standardized amounts and hospital-specific rates for FY 2013, we did not finalize our proposal to apply a −0.8 percent adjustment to the national capital Federal rate until more analysis could be completed (77 FR 53456).

We continue to consider whether MedPAC's recommendation that an adjustment to offset the cumulative documentation and coding effects through FY 2010 under section 1886(d)(3)(A)(iv) of the Act is appropriate and supported by a review of the claims data. As discussed in section II.D.7. of the preamble of this proposed rule, after further consideration of the MedPAC analysis and the requests by public commenters, if we were to apply an additional adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010, we believe the most appropriate additional adjustment is −0.55 percent. While we are not proposing an additional prospective adjustment in FY 2014 for the cumulative MS–DRG documentation and coding effects through FY 2010 at this time, we are soliciting comments on the issue of applying a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS–DRG documentation and coding effect through FY 2010.

Section 631 of the ATRA, discussed in section II.D.6. of the preamble of this proposed rule, amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the operating IPPS standardized amounts 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 to the operating IPPS standardized amounts authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Delaying the implementation of that prospective adjustment to the operating IPPS standardized amounts resulted in overstated payment rates in FYs 2010, 2011, and 2012, and those resulting overpayments could not be recovered under Public Law 110–90. Therefore, under the provisions of section 631 of ATRA, we are proposing a −0.8 percent recoupment adjustment to the operating IPPS standardized amount in FY 2014. Because section 631 of the ATRA requires CMS to make a recoupment adjustment only to the operating IPPS standardized amount, we are not proposing a similar adjustment to the national or Puerto Rico capital IPPS rates (or to the operating IPPS hospital specific rates or 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. In section II.D.7. of the preamble of this proposed rule, we are soliciting public comments as to whether any portion of the aforementioned −0.8 percent recoupment adjustment to the operating IPPS standardized amount should be reduced and instead applied as a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS–DRG documentation and coding effect through FY 2010.

We have consistently stated since the initial implementation of the MS–DRG system that we do not believe it is appropriate for Medicare expenditures under the capital IPPS to increase due to MS–DRG related changes in documentation and coding. We continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate increased Medicare expenditures that result from the effect of any documentation and coding changes due to the implementation of the MS–DRGs, since that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs). As a result, aggregate capital IPPS payments would be inappropriately high because annual aggregate capital IPPS payments are higher than payments that otherwise would have been made through FY 2010 absent the change to the MS–DRGs (77 FR 53456). Because the cumulative documentation and coding effect through FY 2010 results in inappropriately high capital IPPS payments, if we were to apply a prospective adjustment to the operating IPPS standardized amount and the hospital-specific rates to remove this effect, we would also do so for the national capital IPPS Federal rate. This approach would be consistent with our past practice regarding the application of prospective documentation and coding adjustments. In order to make this adjustment to the national capital IPPS Federal rate, as we have done in the past, we would use the Secretary's broad authority under section 1886(g) of the Act to establish and implement the capital IPPS (discussed previously in this preamble), in conjunction with section 1886(d)(3)(A)(vi) of the Act. Therefore, if we attribute a portion of the proposed −0.8 percent recoupment adjustment to the operating IPPS standardized amount for FY 2014 to the prospective adjustment, under the Secretary's broad authority under section 1886(g) of the Act, we would also make an appropriate adjustment to the national capital IPPS Federal rate. The capital IPPS Puerto Rico rate (and operating IPPS Puerto Rico-specific standardized amount) would not be affected as we previously found no significant additional MS–DRG documentation and coding effect through FY 2010 for Puerto Rico that would warrant any additional adjustment (77 FR 53279 and 53457).

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate of Increase in Payments to Excluded Hospitals for FY 2014

Historically, certain hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished 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) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount was multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to certain categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and IPPS-excluded cancer hospitals. IRFs, IPFs, and LTCHs, which were paid previously under the reasonable cost methodology, now receive payment under their own prospective payment systems, in accordance with changes made to the statute. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provided transition periods of varying lengths during which time a portion of the prospective payment was based on cost-based reimbursement rules under 42 CFR Part 413. (However, certain providers do not receive a transition period or may elect to bypass the transition period as applicable under 42 CFR Part 412,

Subparts N, O, and P.) We note that the various transition periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

Certain hospitals excluded from a propective payment system, including children's hospitals and 11 cancer hospitals, continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. In accordance with § 403.752(a) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.

Beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs. As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), with IRFs, IPFs, and LTCHs being paid under their own PPS, the number of providers being paid based on reasonable cost subject to a ceiling, including children's hospitals, 11 cancer hospitals, and RNHCIs, is too small and the cost report data are too limited to be able to create a market basket solely for these hospitals. Therefore, for FY 2014 and subsequent fiscal years, we would continue to use the percentage increase in the IPPS operating market basket to update the target amounts for these cancer hospitals, children's hospitals, and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

However, as described in section IV. of the preamble of this proposed rule, we are proposing to revise and rebase the IPPS operating market basket to a FY 2010 base year. Therefore, we are proposing to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs for FY 2014 and subsequent fiscal years. Accordingly, the FY 2014 rate-of-increase percentage to be applied to the target amount for these cancer hospitals, children's hospitals, and RNHCIs would be the FY 2014 percentage increase in the FY 2010-based IPPS operating market basket. Based on IHS Global Insight, Inc.'s 2013 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2014 is 2.5 percent (that is, the estimate of the market basket rate-of-increase). We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2014.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this proposed rule for the specific proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2014. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

B. Critical Access Hospitals (CAHs): Proposed Changes to the Conditions of Participation Relating to Payment for Inpatient Services

1. Background

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the Essential Access Community Hospitals and Rural Primary Care Hospitals (EACH/RPCH) program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated as a CAH. CAHs participating in the MRHFP must meet the conditions for designation by the State and be certified by the Secretary in accordance with section 1820 of the Act. Further, in accordance with section 1820(e)(3) of the Act, a CAH must meet other criteria that the Secretary specifies.

Among the statutory requirements under section 1820(c) of the Act, a CAH must be located in a rural area (or in an area treated as rural); be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, more than a 15-mile drive) from a hospital or another CAH, unless otherwise designated as a ''necessary provider'' prior to January 1, 2006; have not more than 25 acute care inpatient beds for furnishing inpatient care for a period that does not exceed 96 hours per patient on an annual, average basis; and make available 24-hour emergency care services. The conditions of participation (CoPs) located at 42 CFR Part 485, Subpart F, incorporate these statutory requirements as well as other criteria specified in section 1820(e)(3) of the Act.

2. Proposed Policy Changes

We have received a number of questions from stakeholders in the CAH provider community relating to whether CAHs are required to furnish acute care inpatient services under the CAH CoPs. Our interpretation is that CAHs must provide acute care inpatient services, and we are proposing revisions to clarify and restate this requirement. Using the July 2010 through June 2011 cost reports, we were able to review data for 1,230 of the existing 1,328 CAHs.[59] These data suggest that 99 percent of CAHs are regularly providing acute care inpatient services and are in compliance with such requirements. However, the data regarding the remaining 1 percent, along with the questions we have received, suggest that there may be some service gaps. We further believe that a few CAHs would benefit from clarification of our interpretation that CAHs must furnish acute care inpatient services.

The CAH program was established to improve access for rural residents to essential health care services and particularly hospital services which include acute care inpatient services. We are proposing certain clarifications to ensure continued access to these critical services. Indeed, once a facility has been designated and certified as a CAH, that facility is expected to provide services as a CAH, and it is entrusted with the reliance of the general public and of the local community. When a CAH is not routinely furnishing inpatient services, service gaps arise. For example, we are aware of one instance in the past where a CAH was functioning, in essence, as a nursing home/skilled nursing facility. However, because it was classified as a CAH, it prevented a nearby rural hospital from converting to CAH status in order to continue providing acute care inpatient services to the community. In this case, the CAH in question, instead of assuring critically needed access to acute care inpatient services, not only was not offering such services, but also putting at risk the continued availability of such services in the rural community. We believe the proposed change in regulation in this proposed rule would address these gaps in service by clearly stating that CAHs are required to provide acute care inpatient services.

As set forth in section 1820 of the Act, the CAH program was established to improve access to hospital and other health services for rural residents of a State. We believe that the statutory requirements related to the provision of emergency care and acute care inpatient services, including those at section 1820(c)(2)(B) of the Act, suggest that a CAH must furnish these acute care inpatient services, albeit, in a more limited fashion than would be expected of a hospital. Hospitals are subject to a different set of CoPs, found in 42 CFR part 482.

[59] Produced by the Cecil G. Sheps Center for Health Services Research at the University of North Carolina under a Cooperative Agreement with the Federal ORHP.

We recognize that, given its resources and the needs of the community it serves, a CAH may not be actively treating inpatients at all times. Indeed, the Act fully recognizes the variable nature of a CAH's inpatient census, as it provides specific contingency language for the staffing requirements under section 1820(c)(2)(B)(iv) of the Act. For example, section 1820(c)(2)(B)(iv)(I) requires a CAH to meet the rural hospital staffing requirements under section 1861(e) of the Act, with the exception that the CAH does not need to meet the hospital standards relating to the number of hours per day or days per week when the CAH must be open and fully staffed, except as needed to make available 24-hour emergency care and nursing services, and to staff the CAH whenever an inpatient is present.

We note that a CAH is not specifically required to maintain a minimum average daily census (ADC) of inpatients receiving inpatient acute care services or a minimum number of certified inpatient beds. We are aware that there are significant seasonal variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which a CAH is located. We also recognize the need for inpatient acute care services to be furnished in the best setting for the patient. However, while it is true that CAHs generally are not able to handle patients requiring complex, specialized inpatient services, such as those services provided by trauma centers, or cardiac surgery centers, it is also true that CAHs should be able to handle a range of patient needs requiring admission. We believe it is not in the best interest of patients for them to routinely be transferred to a more distant hospital if instead their care can be provided locally without compromising quality. The blue ''H'' hospital signs posted along the roadways for CAHs serve as public reminders of the services for which CAHs were created to provide.

We also wish to clarify the relationship between a CAH's written policies and the services it offers. The regulations at 42 CFR 485.635(a) require a CAH to furnish health care services in accordance with appropriate written policies. Among other items, the CAH must describe its procedures for emergency medical services and its procedures for inpatient services. Therefore, we expect CAHs to be appropriately prepared to provide the described services. For example, a CAH's policies and procedures should be reflected in the number of certified beds, appropriate equipment, and available staffing (whether as employees or through arrangements or agreements). Similarly, we would expect CAHs to, in fact, be providing the same services outlined in their policies and procedures, as appropriate to the needs of individual patients. To further clarify the interrelated standards at § 485.635(a) and (b) of the regulations, we are proposing to amend the regulatory language at § 485.635(b), as noted below, and we are proposing to revise the language under the standard for ''Patient care policies'' under § 485.635(a)(3)(vii) to remove the conditional phrase ''If a CAH furnishes inpatient services.'' By removing this conditional phrase, we would eliminate regulatory language that could be creating ambiguity where none was intended. The elimination of this language would clarify that CAHs are required to provide acute care inpatient services. Our revision also would align the standard with the structure of neighboring standards under § 485.635(a).

We are proposing to remove paragraph (c)(1)(i) under § 485.635 requiring CAHs to furnish inpatient hospital care services through agreements or arrangements; to redesignate the existing language of paragraph (b)(1) as paragraph (b)(1)(i); and to add a new paragraph (b)(1)(ii) under the standard ''Patient services'' that more clearly requires CAHs to furnish acute care inpatient services. (Because we are proposing to remove paragraph (c)(1)(i), we are proposing to redesignate existing paragraphs (c)(1)(ii) through (c)(1)(iv) as paragraphs (c)(1)(i) through (c)(1)(iii), respectively.)

These proposed clarifying changes are in the spirit of the policies finalized in the May 16, 2012 final rule, ''Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation,'' that sought to reduce outmoded and unnecessarily burdensome regulations, and to increase the ability of CAHs to devote more resources to providing high quality patient care (77 FR 29034). In that final rule, at § 485.635(b), we revised the heading of the standard to read ''Patient services'' instead of ''Direct services'' to specify that a CAH can furnish certain types of services through agreement or arrangements rather than directly. We noted our expectation that furnishing timely services would be best achieved by providing CAH services onsite at the CAH as much as possible, whether through CAH employees or through agreements or arrangements (77 FR 29059). Our proposed addition of paragraph (b)(1)(ii) to § 485.635 would clarify that a CAH must provide acute care inpatient services. We expect that these services would be provided as appropriate to a CAH's resources and as appropriate to meet the needs of its patients. We regard the services furnished in accordance with § 485.635(c) as other additional services, which a CAH may also provide through agreements or arrangements.

Notwithstanding these clarifications and proposed revisions, in accordance with section 1820(d) of the Act, each CAH member of a Rural Health Network would still be required to have an agreement with at least one full-service acute care hospital member of the network regarding patient referral and transfer.

We believe these proposed changes, as discussed above, would address the issues described in this section as well as eliminate existing provider confusion by clearly stating that CAHs are required to provide acute care inpatient services. We expect a CAH to meet all of the conditions of participation under 42 CFR Part 485, including all the standards relating to the furnishing of acute care inpatient services. In the event that a CAH decides that it is no longer able to comply, or that the circumstances no longer warrant compliance, with all of the CAH requirements, such a facility may wish to engage in a dialogue with CMS to explore its options, including avenues other than the CAH program, for continued participation in the Medicare program.

Finally, we are proposing a technical change at § 485.620(a), the section addressing the ''Number of beds'' standard. Specifically, we are proposing to remove the phrase ''after January 1, 2004,'' a prospective effective date established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) and which was subsequently restated in regulation at § 485.620(a) (69 FR 49215). The MMA revised the bed limit upwards, to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. Prior to the MMA, CAHs were restricted to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. Retaining this date in regulation no longer serves the purpose of providing CAHs with notice that they could expand beyond 15 acute care beds. The effective date of January 1, 2004 has passed and the revised maximum bed limit of 25 continues to apply.

VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2014

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 a 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 (LOS) (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 a 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 section VIII. of this preamble, 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, a 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 a 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 2013 rulemaking cycle.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at §§ 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient length of stay of greater than 25 days. 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). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, as consistent with other established hospital prospective payment systems, a 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 as 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. Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

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 as 45 CFR Parts 160 and 162, Subparts A and I through R (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.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2014

1. Background

Section 123 of the BBRA requires that the Secretary implement a PPS for LTCHs (that is, a per discharge system with a diagnosis-related group (DRG)-based patient classification system reflecting the differences in patient resources and costs). 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 such a system [the long-term care hospital (LTCH) PPS] on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients, as well as the use of the most recently available hospital discharge data.''

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 (that is, the CMS DRGs) that was 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 (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. As described in section II.G. of this preamble, for FY 2014, we are not proposing to create or delete any MS–DRGs, and as such we would continue to have a total of 751 MS–DRG groupings for FY 2014. 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 MS–LTC–DRG relative weights.

In a departure from the IPPS, and as discussed in greater detail below in section VIII.B.3.f. of this preamble, we are proposing to continue to use low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 LTCH cases) in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. For purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we are proposing to group all of the low-volume MS–LTC–DRGs into five quintiles based on average charge per discharge. (A detailed discussion of the

initial development and application of the quintile methodology appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).) Under our existing methodology, we are proposing to account for adjustments to payments for 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). Furthermore, we are proposing to make adjustments to account for nonmonotonically increasing weights, when necessary. That is, theoretically, cases under the MS–LTC–DRG system that are more severe require greater expenditure of medical care resources and will result in 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 nonmonotonicity in greater detail and our proposed methodology to adjust the proposed MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights in section VIII.B.3.g. (Step 6) of this preamble.)

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, EKG), or minor surgical procedures (for example, 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.

Through FY 2010, the number of diagnosis and procedure codes considered for MS–DRG assignment was limited to nine and six, respectively. However, for claims submitted on the 5010 format beginning January 1, 2011, we increased the capacity to process diagnosis and procedure codes up to 25 diagnoses and 25 procedures. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. We refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule for a complete discussion of this change (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). Additional coding instructions and examples are published in the *Coding Clinic for ICD–9–CM,* a product of the American Hospital Association. (We refer readers to section II.G.11. of this preamble for additional information on the annual revisions to the ICD–9–CM codes.)

On October 1, 2014, covered entities must begin using the ICD–10–CM and ICD–10–PCS coding systems (45 CFR 162.1102(c)). We have been discussing the conversion to the ICD–10–CM and the ICD–10–PCS coding systems for many years. In prior rules published in the **Federal Register** (for example, section II.G.10. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50128)), we discussed the implementation date for the conversion to the ICD–10–CM and ICD–10–PCS coding systems. We refer readers to section II.G.11. of this preamble for additional information on the implementation of the ICD–10–CM and ICD–10–PCS systems.

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).

Medicare contractors (that is, fiscal intermediaries and 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. Proposed Changes to the MS–LTC–DRGs for FY 2014

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 proposing to update the MS–LTC–DRG classifications effective October 1, 2013, through September 30, 2014 (FY 2014) consistent with the proposed changes to specific MS–DRG classifications presented in section II.G. of this preamble (that is, proposed GROUPER Version 31.0). Therefore, the proposed MS–LTC–DRGs for FY 2014 presented in this proposed rule are the same as the proposed MS–DRGs that are being used under the IPPS for FY 2014. In addition, because the proposed MS–LTC–DRGs for FY 2014 are the same as the proposed MS–DRGs for FY 2014, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed Version 31.0 of the GROUPER discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–9–CM coding system, are also applicable under the LTCH PPS for FY 2014.

3. Development of the Proposed FY 2014 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.

The basic methodology used to develop the proposed MS–LTC–DRG relative weights generally continues to be consistent with the general 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 the modifications to our historical procedures for assigning proposed 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 Proposed MS–LTC–DRG Relative Weights for FY 2014

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53462 through 53467), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2013. The basic methodology we used to develop the FY 2013 MS–LTC–DRG relative weights was the same as the methodology we used to develop the FY 2012 MS–LTC–DRG relative weights in the FY 2012 IPPS/LTCH PPS final rule and was consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). We are proposing to continue to apply our established methodology for FY 2014. Our development of the proposed FY 2014 MS–LTC–DRG relative weights include application of established policies related to the data, the hospital-specific relative value (HSRV) methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustment for nonmonotonicity, and the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor. Below we present the methodology that we are proposing to continue to use to determine the MS–LTC–DRG relative weights for FY 2014, which is consistent with the methodology presented in the FY 2013 IPPS/LTCH PPS final rule.

Beginning with the FY 2008 update, we established a budget neutrality requirement for 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). Consistent with § 412.517(b), we are proposing to continue to apply our established two-step budget neutrality methodology, which is based on the current year MS–LTC–DRG classifications and relative weights. We are proposing to continue to apply our established two-step budget neutrality methodology such that the annual update to the MS–LTC–DRG classifications and relative weights for FY 2014 are based on the FY 2013 MS–LTC–DRG classifications and relative weights established in Table 11 listed in section VI. of the Addendum to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53716 through 53717). (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).)

c. Data

For this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2014, we are proposing to obtain total charges from FY 2012 Medicare LTCH bill data from the December 2012 update of the FY 2012 MedPAR file, which are the best available data at this time, and to use the proposed Version 31.0 of the GROUPER to classify LTCH cases. Consistent with our existing methodology, we also are proposing that

if more recent data become available, we would use those data and the finalized Version 31.0 of the GROUPER in establishing the FY 2014 MS–LTC–DRG relative weights in the final rule. Consistent with our historical methodology, we are proposing to exclude the data from 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. Furthermore, consistent with our historical practice, we are proposing to exclude Medicare Advantage (Part C) claims, which are now included in the MedPAR files, in the calculations for the proposed relative weights under the LTCH PPS that are used to determine payments for Medicare fee-for-service claims. Specifically, we are proposing not to use any claims from the MedPAR files that have a GHO Paid indicator value of ''1,'' which effectively removes Medicare Advantage claims from the proposed relative weight calculations (73 FR 48532). Accordingly, in the development of the proposed FY 2014 MS–LTC–DRG relative weights in this proposed rule, we excluded the data of 14 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with demonstration projects that had claims in the December 2012 update of the FY 2012 MedPAR file, as well as any Medicare Advantage claims.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and treatment of infections and wound care. Some case types (MS–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, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2014. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduce the impact of the variation in charges across providers on any particular proposed MS–LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each case to hospital-specific relative charge values and then adjust 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, so 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 cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with our established methodology, under this proposal, we would continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VIII.B.3.g. (Step 3) of this preamble) by the average adjusted charge for all cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case (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 standardize 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.

e. Proposed Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the proposed 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. MS–LTC–DRGs with at least 25 cases are each assigned a unique relative weight; low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 cases based on a given year's claims data) are grouped into quintiles (as described below) and assigned the relative weight of the quintile. No-volume MS–LTC–DRGs (that is, no cases in the given year's claims data are assigned to those MS–LTC–DRGs) 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). We are proposing to continue to utilize these same three categories of MS–LTC–DRGs for purposes of the treatment of severity levels in determining the proposed MS–LTC–DRG relative weights for FY 2014. (We provide in-depth discussions of our policy regarding weight-setting for proposed low-volume MS–LTC–DRGs in section VIII.B.3.f. of the preamble of this proposed rule and for proposed no-volume MS–LTC–DRGs, under Step 5 in section VIII.B.3.g. of this preamble.)

Furthermore, in determining the proposed FY 2014 MS–LTC–DRG relative weights, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VIII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), consistent with our existing methodology for purposes of determining the proposed FY 2014 MS–LTC–DRG relative weights, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we

group the proposed ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contained between 1 and 24 cases annually) into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In determining the proposed FY 2014 MS–LTC–DRG relative weights in this proposed rule, in cases where the initial assignment of a proposed low-volume MS–LTC–DRG to quintiles results in nonmonotonicity within a base-DRG, in order to ensure appropriate Medicare payments, consistent with our historical methodology, we are proposing to make adjustments to the treatment of proposed low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VIII.B.3.g. (Step 6) of this preamble.

In this proposed rule, using LTCH cases from the December 2012 update of the FY 2012 MedPAR file (which is currently the best available data), we identified 280 MS–LTC–DRGs that contained between 1 and 24 cases. This list of proposed MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing 56 proposed MS–LTC–DRGs (280/5 = 56 with no proposed MS–LTC–DRGs as the remainder). We are proposing to assign a proposed low-volume MS–LTC–DRG to a specific low-volume quintile by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of proposed MS–LTC–DRGs with less than 25 cases was evenly divisible by 5. However, had the number of proposed MS–LTC–DRGs with less than 25 cases not been evenly divisible by 5, consistent with our historical approach we would have used the average charge of the low-volume quintile to determine which of the low-volume quintiles contain the additional low-volume MS–LTC–DRGs. (For an example of the application of this approach, we refer readers to the discussion of the treatment of the low-volume MS–LTC–DRGs for FY 2013 (77 FR 53463).) Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we are proposing to assign the first fifth (1st through 56th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The proposed MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. Table 13A, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the composition of the proposed low-volume quintiles for proposed MS–LTC–DRGs for FY 2014.

Accordingly, in order to determine the proposed FY 2014 relative weights for the proposed MS–LTC–DRGs with low volume, we are proposing to use the five low-volume quintiles described above. We determined a proposed relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology that we applied to the proposed MS–LTC–DRGs (25 or more cases), as described below in section VII.B.3.g. of this preamble. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low volume of LTCH cases will vary in the future.

Furthermore, we note that we will continue to monitor the volume (that is, the number of LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the proposed MS–LTC–DRG relative weights result in appropriate payment for such cases and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2014 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to determine the FY 2014 MS–LTC–DRG relative weights based on our existing methodology. (For additional information on the original development of this methodology, and modifications to it since the adoption of the MS–LTC–DRGs, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55995) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43951 through 43966).) In summary, to determine the proposed FY 2014 MS–LTC–DRG relative weights, we are proposing to group LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the low-volume quintile (as described above). After grouping the cases to the appropriate MS–LTC–DRG (or low-volume quintile), we calculate the proposed FY 2014 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (Steps 1 and 2 below). Next, we adjust the number of cases in each proposed MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing statistical outliers (Step 1 below) and cases with a length of stay of 7 days or less (Step 2 below), the SSO adjusted discharges and corresponding charges were then used to calculate ''relative adjusted weights'' for each proposed MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the proposed FY 2014 MS–LTC–DRG relative weights. We note that, as we discussed in section VIII.B.3.c. of this preamble, we excluded the data of all-inclusive rate LTCHs, LTCHs that are paid in accordance with demonstration projects, and any Medicare Advantage claims in the December 2012 update of the FY 2012 MedPAR file.

Step 1—Remove statistical outliers.

The first step in the calculation of the proposed FY 2014 MS–LTC–DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the MS–LTC–DRGs. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—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 proposed FY 2014 MS–LTC–DRG relative weights, the value of many proposed relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a

LTCH by including data from these very short stays. Therefore, consistent with our historical relative weight methodology, in determining the proposed FY 2014 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Adjust charges for the effects of SSOs.

After removing cases with a length of stay of 7 days or less, we are left with cases that have a length of stay of greater than or equal to 8 days. As the next step in the calculation of the proposed FY 2014 MS–LTC–DRG relative weights, consistent with our historical relative weight methodology, we are proposing to adjust each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503).

We are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full discharges with no adjustment in determining the proposed FY 2014 MS–LTC–DRG relative weights would lower the proposed FY 2014 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within an MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are proposing to adjust for SSO cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2014 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2014 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we are proposing to calculate a hospital-specific relative charge value by dividing the SSO adjusted charge per discharge (see Step 3) of the LTCH case (after removing the statistical outliers (see Step 1) and LTCH cases with a length of stay of 7 days or less (see Step 2)) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS–LTC–DRG, we are proposing to calculate the proposed FY 2014 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the proposed MS–LTC–DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated proposed MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) is calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values (from above) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process is continued until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2014 relative weight for MS–LTC–DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed FY 2014 relative weight for each proposed MS–LTC–DRG using total Medicare allowable total charges reported in the best available LTCH claims data (that is, the December 2012 update of the FY 2012 MedPAR file for this proposed rule). Using these data, we identified the proposed MS–LTC–DRGs for which there were no LTCH cases in the database, such that no patients who would have been classified to those proposed MS–LTC–DRGs were treated in LTCHs during FY 2012 and, therefore, no charge data were available for these proposed MS–LTC–DRGs. Thus, in the process of determining the proposed MS–LTC–DRG relative weights, we are unable to calculate proposed relative weights for the proposed MS–LTC–DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are proposing to assign a relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of proposed ''transplant'' MS–LTC–DRGs and proposed ''error'' 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.)

In general, we are proposing to determine proposed FY 2014 relative weights for the proposed MS–LTC–DRGs with no LTCH cases in the December 2012 update of the FY 2012 MedPAR file used in this proposed rule (that is, proposed ''no-volume'' MS–LTC–DRGs) by cross-walking each proposed no-volume MS–LTC–DRG to another proposed MS–LTC–DRG with a calculated proposed relative weight (determined in accordance with the methodology described above). Then, the proposed ''no-volume'' MS–LTC–DRG is assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 751 proposed MS–LTC–DRGs for FY 2014, we identified 236 proposed MS–LTC–DRGs for which there are no LTCH cases in the database (including the 8 proposed ''transplant'' MS–LTC–DRGs and 2 proposed ''error'' MS–LTC–DRGs). As stated above, we are proposing to assign proposed relative weights for each of the 236 proposed no-volume MS–LTC–DRGs (with the exception of the 8 proposed ''transplant'' MS–LTC–DRGs and the 2 proposed ''error'' MS–LTC–DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 515 (751—236= 515) proposed MS–LTC–DRGs for which we are able to determine proposed relative weights based on FY 2012 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the proposed ''cross-walked'' MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we crosswalk one of the 236 proposed ''no volume'' MS–LTC–DRGs, with the exception of the 8 proposed ''transplant'' MS–LTC–DRGs and the 2 proposed ''error'' MS–LTC–DRGs, for purposes of determining a proposed relative weight.) Then, we are proposing

to assign the proposed no-volume MS–LTC–DRG the proposed relative weight of the proposed cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

For this proposed rule, we are proposing to cross-walk the proposed no-volume MS–LTC–DRG to a proposed MS–LTC–DRG for which there are LTCH cases in the December 2012 update of the FY 2012 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. We evaluated the relative costliness in determining the applicable proposed MS–LTC–DRG to which a proposed no-volume MS–LTC–DRG is cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS–LTC–DRGs in FY 2014. (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 proposed no-volume MS–LTC–DRGs in FY 2014, the proposed relative weights assigned based on the proposed cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the proposed crosswalks, which are based on similar clinical similarity and relative costliness, generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the proposed cross-walked MS–LTC–DRG as the proposed relative weight for the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2014. We note that if the proposed cross-walked MS–LTC–DRG had 25 cases or more, its proposed relative weight, which is calculated using the proposed methodology described in Steps 1 through 4 above, is assigned to the proposed no-volume MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the proposed no-volume MS–LTC–DRG is cross-walked has 24 or less cases and, therefore, is designated to one of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2014. (As we noted above, in the infrequent case where nonmonotonicity involving a proposed no-volume MS–LTC–DRG results, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the proposed no-volume MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each is cross-walked (that is, the proposed cross-walked MS–LTC–DRGs) for FY 2014 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

To illustrate this methodology for determining the proposed relative weights for the FY 2014 MS–LTC–DRGs with no LTCH cases, we are providing the following example, which refers to the proposed no-volume MS–LTC–DRGs crosswalk information for FY 2014 provided in Table 13B.

Example: There are no cases in the FY 2012 MedPAR file used for this proposed rule for proposed MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) was similar clinically and based on resource use to proposed MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight of proposed MS–LTC–DRG 70 of 0.8222 for FY 2014 to proposed MS–LTC–DRG 61 (obtained from Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume of LTCH cases based on the system will vary in the future. We used the most recent available claims data in the MedPAR file to identify proposed no-volume MS–LTC–DRGs and to determine the proposed relative weights in this proposed rule.

Furthermore, for FY 2014, consistent with our historical relative weight methodology, we are proposing to establish the proposed MS–LTC–DRG relative weight of 0.0000 for the following proposed 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 proposed transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these proposed 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).)

Step 6—Adjust the proposed FY 2014 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 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 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, proposed relative weights should increase by severity, from lowest to highest. If the proposed

relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher proposed relative weight than one with MCC, or the proposed 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). Consequently, in determining the proposed FY 2014 MS–LTC–DRG relative weights in this proposed rule, consistent with our historical methodology, we are proposing to combine MS–LTC–DRG severity levels within a base proposed MS–LTC–DRG for the purpose of computing a proposed relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2014 MS–LTC–DRG relative weights in this proposed rule by applying this proposed methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

Step 7—Calculate the proposed FY 2014 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 proposing to update the MS–LTC–DRG classifications and relative weights for FY 2014 based on the most recent available LTCH data, and apply a budget neutrality adjustment in determining the proposed FY 2014 MS–LTC–DRG relative weights.

To ensure budget neutrality in the proposed update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. In this proposed rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2014, we are proposing to calculate and apply a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not influenced 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 proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average CMI.

To calculate the proposed normalization factor for FY 2014 (the first step of our budget neutrality methodology), we are proposing to use the following three steps: (1.a.) we use the most recent available LTCH claims data (FY 2012) and group them using the proposed FY 2014 GROUPER (Version 31.0) and the recalibrated proposed FY 2014 MS–LTC–DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the Proposed FY 2014 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we group the same LTCH claims data (FY 2012) using the FY 2013 GROUPER (Version 30.0) and FY 2013 MS–LTC–DRG relative weights and calculate the average CMI; and (1.c.) we compute the ratio of these average CMIs by dividing the average CMI for FY 2013 (determined in Step 1.b.) by the proposed average CMI for FY 2014 (determined in Step 1.a.). In determining the proposed MS–LTC–DRG relative weights for FY 2014, each recalibrated MS–LTC–DRG relative weight is multiplied by 1.11546 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced proposed ''normalized relative weights.''

In the second step of our proposed MS–LTC–DRG budget neutrality methodology, we are proposing to determine a budget neutrality factor to ensure that estimated aggregate LTCH PPS payments (based on the most recent available LTCH claims data) after reclassification and recalibration (that is, the proposed FY 2014 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2013 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2012 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2013 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2014 MS–LTC–DRGs and relative weights. Specifically, for this proposed rule, as discussed previously in section VIII.B.3.c. of this preamble, we are using LTCH claims data from the December 2012 update of the FY 2012 MedPAR file, as these are the best available data at this time. Furthermore, consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to determine the budget neutrality adjustment factor for FY 2014 in the final rule.

For this proposed rule, we are proposing to determine the proposed FY 2014 budget neutrality adjustment factor using the following three steps: (2.a.) we simulate estimated total LTCH PPS payments using the proposed normalized relative weights for FY 2014 and proposed GROUPER Version 31.0 (as described above); (2.b.) we simulate estimated total LTCH PPS payments using the FY 2013 GROUPER (Version 30.0) and the FY 2013 MS–LTC–DRG relative weights in Table 11 of the Addendum to the FY 2013 IPPS/LTCH PPS final rule available on the Internet (76 FR 53716); and (2.c.) we calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2013 GROUPER (Version 30.0) and the FY 2013 MS–LTC–DRG relative weights (determined in Step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2014 GROUPER (Version 31.0) and the proposed normalized MS–LTC–DRG relative weights for FY 2014 (determined in Step 2.a.). In determining the proposed FY 2014 MS–LTC–DRG relative weights, each proposed normalized relative

weight is multiplied by a proposed budget neutrality factor of 0.9953277 (determined in Step 2.c.) in the second step of the budget neutrality methodology to determine the proposed budget neutral FY 2014 relative weight for each MS–LTC–DRG.

Accordingly, in determining the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.11546 and a budget neutrality factor of 0.9953277 (computed as described above). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the proposed MS–LTC–DRGs and their respective proposed 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 proposed ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2014 (and reflect both the proposed normalization factor of 1.11546 and the proposed budget neutrality factor of 0.9953277).

C. Proposed LTCH PPS Payment Rates for FY 2014

1. Overview of Development of the LTCH Payment Rates

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal rate for FY 2014, that is, effective for LTCH discharges occurring on or after October 1, 2013 through September 30, 2014.

For further details on the development of the FY 2003 standard Federal rate when the LTCH PPS was initially implemented, 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); and FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481).

The proposed update to the LTCH PPS standard Federal rate for FY 2014 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2014 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for fiscal year FY 2014 as required by the statute (as discussed below in section VIII.C.2.c. of this preamble). Furthermore, as discussed below in section VIII.C.3. of this preamble, for FY 2014, in addition to the proposed update factor, under the second year of the 3-year phase-in under the current regulations at § 412.523(d)(3), we are proposing to make a one-time prospective adjustment to the standard Federal rate for FY 2014 so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years . In addition, as discussed in section V.A. of the Addendum of this proposed rule, we are proposing to make an adjustment to the standard Federal rate to account for the estimated effect of the proposed changes to the area wage level adjustment for FY 2014 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4). (We refer readers to the discussion of the proposed reduction to the annual update for LTCHs that fail to submit quality reporting data in section VIII.C.2.c. of this preamble, the proposed application of the one-time prospective adjustment under the second year of the 3-year phase-in in section VIII.C.3. of this preamble, and the proposed budget neutrality adjustment for changes in the area wage levels in section V.A. of the Addendum of this proposed rule.)

2. Proposed FY 2014 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) and this preamble.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the standard Federal rate and refers to the timeframes associated with such adjustments as a ''rate year'' (which are discussed in more detail in section VIII.C.2.b. of this preamble.) 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, 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 standard Federal 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 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. The MFP adjustment is derived using a projection of MFP that is currently produced by IHS Global Insight, Inc. (For additional details on the development of the MFP adjustment and its application under the LTCH PPS, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51691 through 51692 and 51770 through 51771).)

For FY 2014, we are proposing to continue to use our methodology for calculating and applying the proposed MFP adjustment to determine the annual update to the LTCH PPS standard Federal rate for FY 2014. (For details on the development of the MFP adjustment, including our finalized methodology for calculating and applying the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692).)

c. Adjustment to the Annual Update to the LTCH PPS Standard Federal Rate Under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Background

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 (LTCHQR) Program. (As noted above, 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.) Under the LTCHQR Program, as required by section 1886(m)(5)(A)(i) of the Act, for FY 2014 and each subsequent year, in the case of a 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, any annual update to a standard Federal rate for discharges for the hospital during the year, and after application of section 1886(m)(3) of the Act, shall be reduced by 2.0 percentage points. Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to the FY 2014 payment determination no later than October 1, 2012. Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made 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 that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a measure(s) that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756). In that same final rule as discussed in section IX.C. of the preamble of this proposed rule, we adopted the following three quality measures for the FY 2014 payment determination: Urinary Catheter-Associated Urinary Tract Infection (CAUTI) rate per 1, 000 urinary catheter days, for Intensive Care Unit Patients (NQF #013); Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery Patients (NQF #0139); and Percent of Residents with Pressure Ulcers That are New or Worsened (Application of NQF #0678). For additional discussion and details of the history of the LTCHQR Program, including the statutory authority and further details on the three measures previously finalized for the FY 2014 payment determination, we refer readers to section IX.C. of the preamble of this proposed rule and to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. Proposed Reduction to the Annual Update to the LTCH PPS Standard Federal Rate Under the LTCHQR Program

Consistent with section 1886(m)(5)(A)(i) of the Act, for FY 2014 and subsequent fiscal years, we are proposing that for LTCHs that do not submit quality reporting data under the LTCHQR Program with respect to such a fiscal year, any annual update to a standard Federal rate for discharges for the LTCH during the fiscal year and after application of the market basket update adjustments required by section 1886(m)(3) of the Act, would be further reduced by 2.0 percentage points. That is, in establishing an update to the LTCH PPS standard Federal rate for FY 2014 and subsequent fiscal years, the full LTCH PPS market basket increase estimate, subject to an adjustment based on changes in economy-wide productivity (''the MFP adjustment'') 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, would be further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data under the LTCHQR Program. Accordingly, in this proposed rule, we are proposing to implement the reduction in the annual update to the LTCH PPS standard Federal rate for failure to report quality data under the LTCHQR Program for FY 2014 and subsequent fiscal years under proposed § 412.523(c)(4). Specifically, consistent with section 1886(m)(5)(A)(i) of the Act, under proposed § 412.523(c)(4)(i), we are proposing that for a LTCH that does not submit quality reporting data in the form and manner and at the time specified by the Secretary under the

LTCHQR Program, the annual update to the standard Federal rate under § 412.523(c)(3) would be further reduced by 2.0 percentage points. (Note, as discussed previously this section, the annual update to the standard Federal rate implemented under § 412.523(c)(3) reflects the application of the adjustments to any annual update as required by sections 1886(m)(3) and (m)(4) of the Act.) In addition, under proposed § 412.523(c)(4)(ii), consistent with section 1886(m)(5)(A)(ii) of the Act, we are proposing that any reduction of the annual update to the standard Federal rate under proposed § 412.523(c)(4)(i) would apply only to the fiscal year involved and would not be taken into account in computing the annual update to the standard Federal rate for a subsequent fiscal year. Lastly, consistent with section 1886(m)(5)(B) of the Act, under proposed § 412.523(c)(4)(iii), we are proposing that the application of any reduction of the annual update to the standard Federal rate under proposed § 412.523(c)(4)(i) may result in an annual update that would be less than 0.0 percent for a fiscal year, and may result in payment rates for a fiscal year that would be less than such payment rates for the preceding rate year.

We also discuss this proposed application of the 2.0 percentage point reduction under proposed § 412.523(c)(4)(i) in our discussion of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2014 below in section VIII.C.2.e. of this preamble.

d. Proposed Market Basket Under the LTCH PPS for FY 2014

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53468), 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 2014, we are proposing to continue to use the FY 2009-based LTCH-specific market basket to update the LTCH PPS for FY 2014. 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).

e. Proposed Annual Market Basket Update for LTCHs for FY 2014

Consistent with our historical practice, we are proposing to estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's first quarter 2013 forecast, the proposed FY 2014 full market basket estimate for the LTCH PPS using the FY 2009-based LTCH-specific market basket is 2.5 percent. Using our established methodology for determining the MFP adjustment, the current estimate of the MFP adjustment for FY 2014 based on IGI's first quarter 2013 forecast is 0.4 percent (for additional details, we refer readers to section V.A.1. of this preamble). Consistent with our historical practice of using the best available data, we are proposing that if more recent data become available to determine the market basket estimate or the MFP adjustment, we would use such data for the final rule, if appropriate.

For FY 2014, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the standard Federal rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full FY 2014 market basket update by the FY 2014 MFP adjustment. To determine the market basket update for LTCHs for FY 2014, as reduced by the proposed MFP adjustment, consistent with our established methodology, we are proposing to subtract the FY 2014 MFP adjustment from the FY 2014 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(D) of the Act requires that any annual update to the standard Federal rate for FY 2014 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.3 percentage point for FY 2014. Therefore, following application of the productivity adjustment, we are proposing to reduce the proposed 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).)

As discussed previously in section VIII.C.2.c. of this preamble, for FY 2014, section 1886(m)(5) of the Act requires that for LTCHs that do not submit quality reporting data under the LTCHQR Program, any annual update to a standard Federal rate, after application of the adjustments required by section 1886(m)(3) of the Act, will be further reduced by 2.0 percentage points. Therefore, the proposed update to the LTCH PPS standard Federal rate for FY 2014 for LTCHs that fail to submit quality reporting data under the LTCHQR Program, 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 proposed rule, in accordance with the statute we are proposing to reduce the proposed FY 2014 full market basket estimate of 2.5 percent (based on the first quarter 2013 forecast of the FY 2009-based LTCH-specific market basket) by the proposed FY 2014 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2014, as described in section V.A.1. of the preamble of this proposed rule) of 0.4 percentage point (based on IGI's first quarter 2013 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 2.1 percent (2.5 percent minus 0.4 percentage point) is then reduced by 0.3 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(D) of the Act. Therefore, in this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish an annual market basket update under the LTCH PPS for FY 2014 of 1.8 percent (that is, the most recent estimate of the LTCH PPS market basket update at this time of 2.5 percent less the MFP adjustment of 0.4 percentage point less the 0.3 percentage point required under section 1886(m)(4)(D) of the Act), provided the LTCH submits quality reporting data in accordance with section 1886(m)(5) of the Act (as discussed above in section VIII.C.2.c. of this preamble). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (x), which specifies that the standard Federal rate for FY 2014 is the standard Federal rate for the previous LTCH PPS year updated by 1.8 percent,

and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCHQR Program, under proposed § 412.523(c)(3)(x) in conjunction with proposed § 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act (as discussed previously in section VIII.C.2.c. of this preamble). Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of −0.2 percent (that is, 1.8 percent minus 2.0 percentage points) for FY 2014 for LTCHs that fail to submit quality reporting data under the LTCHQR Program. As stated above, consistent with our historical practice of using the most recent available data, we are proposing that, if more recent data become available when we develop the final rule, we would use such data, if appropriate, in determining the final market basket update under the LTCH PPS for FY 2014. (We note that we also are proposing to adjust the FY 2014 standard Federal rate by the proposed application of the one-time prospective adjustment under the second year of the 3-year phase-in under § 412.523(d)(3) (discussed below in section VIII.C.3. of this preamble) and by a proposed 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 proposed rule).)

3. Proposed Adjustment for the Second Year of the Phase-In of the One-Time Prospective Adjustment to the Standard Federal Rate Under § 412.523(d)(3)

We set forth regulations implementing the LTCH PPS, based upon the broad authority granted to the Secretary, under section 123 of the BBRA (as amended by section 307(b) of the BIPA). Section 123(a)(1) of the BBRA required that the system ''maintain budget neutrality'' in the August 30, 2002 LTCH PPS final rule (67 FR 55954). The statutory budget neutrality requirement means that estimated aggregate payments under the LTCH PPS for FY 2003 would be equal to the estimated aggregate payments that would have been made if the LTCH PPS were not implemented for FY 2003. The methodology for determining the LTCH PPS standard Federal rate for FY 2003 that would ''maintain budget neutrality'' is described in considerable detail in the August 30, 2002 final rule (67 FR 56027 through 56037). Our methodology for estimating payments for the purposes of budget neutrality calculations used the best available data, and necessarily reflected several assumptions (for example, costs, inflation factors, and intensity of services provided) in estimating aggregate payments that would have been made if the LTCH PPS had not been implemented (without accounting for certain statutory provisions that affect the level of payments to LTCHs in years prior to the implementation of the LTCH PPS, as required by the statute).

In the August 30, 2002 final rule, we also stated our intentions to monitor LTCH PPS payment data to evaluate whether later data varied significantly from the data available at the time of the original budget neutrality calculations (for example, data related to inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent the later data significantly differed from the data employed in the original calculations, the aggregate amount of payments during FY 2003 based on later data may be higher or lower than the estimates upon which the budget neutrality calculations were based. Therefore, in that same final rule, under the broad authority conferred upon the Secretary in developing the LTCH PPS, including the authority for establishing appropriate adjustments, under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, we provided in § 412.523(d)(3) of the regulations for the possibility of making a one-time prospective adjustment to the LTCH PPS rates, so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53487 through 53488) for a complete discussion of the history of the development of the one-time prospective adjustment to the LTCH PPS standard Federal rate at § 412.523(d)(3).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53495), we finalized our policy to make a one-time prospective adjustment to the standard Federal rate so that it will be permanently reduced by approximately 3.75 percent to account for the estimated difference between projected aggregate FY 2003 LTCH PPS payments and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented. Specifically, using the methodology we adopted in that same final rule, we determined that permanently applying a factor of 0.9625 (that is, a permanent reduction of approximately 3.75 percent) to the standard Federal rate is necessary to ensure estimated total FY 2003 LTCH PPS payments equal estimated total FY 2003 TEFRA payments consistent with our stated policy goal of the one-time prospective adjustment under § 412.523(d)(3) (that is, to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years). (We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53487 through 53502) for a complete discussion of the evaluation approach, methodology, and determination of the one-time prospective adjustment to the LTCH PPS standard Federal rate at § 412.523(d)(3).)

Given the magnitude of this adjustment, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53501 through 53502), under § 412.523(d)(3), we established a policy to phase-in the permanent adjustment of 0.9625 to the standard Federal rate over a 3-year period. To achieve a permanent adjustment of 0.9625, under the phase-in of this adjustment, in that same final rule, we explained that we will apply a factor of 0.98734 to the standard Federal rate in each year of the 3-year phase-in, that is, in FY 2013 (which does not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law), FY 2014, and FY 2015. By applying a permanent factor of 0.98734 to the standard Federal rate in each year for FYs 2013, 2014, and 2015, we will completely account for the entire adjustment by having applied a cumulative factor of 0.9625 (calculated as $0.98734 \times 0.98734 \times 0.98734 = 0.9625$) to the standard Federal rate. Accordingly, in accordance with the existing regulations at § 412.523(d)(3), we are proposing to apply a permanent factor of 0.98734 for FY 2014 to the standard Federal rate under the second year of the 3-year phase-in of the one-time prospective adjustment. (The proposed LTCH PPS standard Federal rate for FY 2014 is presented in section V.A. of the Addendum to this proposed rule.)

D. Expiration of Certain Payment Rules for LTCH Services—The 25-Percent Threshold Payment Adjustment

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 provided for a 5-year moratorium on the full application of the 25-percent payment adjustment threshold policy that expired for some LTCHs and LTCH

satellites for cost reporting periods beginning on or after October 1, 2012 (''October'' LTCHs) and for other LTCHs and LTCH satellites for cost reporting periods beginning on or after July 1, 2012 (''July'' LTCHs). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53483 through 53484) as amended by the FY 2013 IPPS/LTCH PPS correcting amendment (77 FR 63751 through 63753), we provided for extensions to the expiring statutory moratoria for both ''October'' and ''July'' LTCHs and LTCH satellites.

Specifically, we established a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) on the full application of the 25-percent threshold payment adjustment policy for ''October'' LTCHs, and for those ''July'' LTCHs that would have been affected by the ''gap'' between the expiration of the statutory moratorium (for cost reporting periods beginning on or after July 1, 2012) and our prospective regulatory relief (for cost reporting periods beginning on or after October 1, 2012) we also provided for an additional moratorium based on LTCH discharges occurring on or after October 1, 2012 and ending at the start of their next cost reporting period. For those ''July'' LTCHs with cost reporting periods beginning on or after October 1, 2012, the regulatory extension of the statutory moratorium, described above, effective for the hospital's first cost reporting period beginning on or after October 1, 2012, resulted in seamless coverage for that group. But for those ''July'' LTCHs with cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012, that would have otherwise been subject to the ''gap'' between the expiration of the statutory moratorium and the effective date of the regulatory moratoria we established a second regulatory moratorium effective with discharges occurring beginning October 1, 2012, through the end of the hospital cost reporting period (that is, the end of the cost reporting period that began on or after July 1, 2012, and before October 1, 2012). For more details about these moratoriums, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53483 through 53484).

Under current law, the regulatory moratorium on the full application of the 25-percent threshold payment adjustment policy will expire for all LTCHs (both ''October'' and ''July'' LTCHs) for cost reporting periods beginning on or after October 1, 2013. As discussed in greater detail below, we do not anticipate further extending the regulatory moratorium of the 25-percent threshold payment adjustment policy. Therefore, LTCHs are encouraged to familiarize themselves with the prior rulemakings that established the adjustments for the various types of LTCHs and LTCH satellites. (We refer readers to the FY 2005 IPPS final rule (69 FR 49205 through 49214) and the RY 2007 LTCH PPS final rule (72 FR 26929). We note that the 25-percent threshold payment adjustment policy does not apply to ''subclause (II)'' LTCHs, that is, an LTCH described under section 1886(d)(1)(B)(iv)(II) of the Act as implemented at § 412.23(e)(2)(ii) of the regulations. Subclause (II) LTCHs meeting that definition continue to be exempted from this policy.

While we could propose further extending the regulatory moratoria, we do not believe it would be appropriate to do so. We are allowing the moratoria to expire because we continue to be concerned that LTCHs that admit more than the applicable percentage of patients from a particular referring hospital are, in effect, behaving like step-down units of the referring hospital, and that results in two separate Medicare payments—one to the referring hospital and one to the LTCH—for what we believe should be structured as one episode of care. In light of our duties to protect the fiscal integrity of the Medicare program, we believe that it would be inappropriate to continue to offer the mortaria pending the implementation of the policy outcomes of the research described below. We welcome public comments on this approach.

In section VIII.E. of the preamble of this proposed rule we present interim results of CMS' research initiatives that have been directed towards studying the different types of patients presently treated at LTCHs, and the potential options for establishing LTCH patient-level criteria. Although we are not proposing any policy changes based on the described research at this time, we indicate that such a policy might obviate the need for the 25-percent threshold payment adjustment policy. Therefore, we are inviting public comments on that possibility.

E. Research on the Development of a Patient Criteria-Based Payment Adjustment Under the LTCH PPS

1. Overview

CMS has been researching the development of patient and/or facility-level criteria for LTCHs, as originally recommended by MedPAC in its June 2004 Report to the Congress, ''New Approaches in Medicare.'' In that report, MedPAC recommended such criteria in the report's fifth chapter on ''Defining long-term care hospitals'' (p. 121 through 135). This report is hereinafter referred to as the MedPAC 2004 Report. Section 114(a) of the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007, which added section 1861(ccc) to the Act, specified certain facility-level criteria for LTCHs. Therefore, we generally focused our subsequent research initiatives on the development of potential LTCH patient-level criteria.

In the FY 2013 IPPS/LTCH PPS proposed rule, we noted that two research projects were currently underway that we believed could potentially result in ''. . . revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary'' (77 FR 28022). In the FY 2013 IPPS/LTCH PPS final rule, we noted that, ''. . . [w]e continue to share MedPAC's concerns regarding the treatment of medically appropriate patients in LTCHs'' (77 FR 53485). We quoted MedPAC's March 2012 Report to Congress, ''Medicare Payment Policy,'' in which MedPAC noted, ''. . . if medically complex cases in LTCHs are, in essence, indistinguishable from medically complex cases in acute care hospitals, then Medicare must ensure that its payments for the same set of services are equitable, regardless of where the services are provided . . . policymakers must consider whether certain models of care will best serve the needs of medically complex patients. These steps will help ensure that Medicare beneficiaries receive appropriate, high quality care in the least costly setting consistent with their clinical conditions'' (77 FR 53485).

We agreed with MedPAC's assertions, and further noted our ongoing research that focused on determining whether there were some patient-level criteria that could be used to identify patients that are appropriately treated in a LTCH, consistent with their higher costs. At that time we shared our contractors' preliminary findings that, ''. . . focusing on a subset of patients who are 'chronically critically ill,' that is who have been in intensive or coronary care units for a significant period of time at IPPS hospitals immediately preceding the admission to the LTCH may prove to be an important step at this point.'' In the final rule we ended our response to the comments received with the following assurance: ''[a]s we have in the past, when this research reaches the appropriate stage, we intend to reach out to hospital industry stakeholders for reactions and feedback'' (77 FR 53485).

In this proposed rule, we are describing the preliminary findings of this ongoing research that is being conducted by Kennell and Associates (Kennell) and its subcontractor, RTI, under the guidance of CMS' Center for Medicare and Medicaid Innovation (the Innovation Center). We believe that this project, in large part, establishes a framework that can potentially be used to empirically identify the population of Medicare beneficiaries who we believe should form the core of LTCH patients appropriate for higher Medicare payments under the LTCH PPS. Although this research has not been completed, we believe that the preliminary findings suggest that certain types of patients, who are chronically critically ill and considered medically complex, as identified by specific clinical factors, are more appropriate candidates for high-cost treatment at a LTCH than other types of patients. It is worth noting that this is the same population that the LTCH industry in discussions with CMS has repeatedly defined as its target population.

The framework, described below, represents the latest research for refining the LTCH PPS. Historically CMS refinements have included the input of advocates for the LTCH industry and MedPAC, as well as CMS and its contractors. We hope that they will continue to offer their insights to the framework presented below as well, and CMS will continue to take into consideration all stakeholders' input. However, we emphasize that we are not proposing a new payment policy at this time. Rather, we are interested in receiving feedback from the public on the findings of this research study and also on the potential impact that our framework could have on hospital markets with the expectation of formulating a proposal for FY 2015.

In the discussion below, we provide a summary of the research findings, discuss issues presented by our analyses of Medicare data from LTCHs and other hospital-level providers, describe the steps that led to our contractor's findings, and present the resulting framework and our current understanding of the likely impact of this work on the Medicare payment system if we were to implement this framework.

2. MedPAC's 2004 Report to the Congress

Within a year of CMS' implementation of the LTCH PPS, MedPAC noted in its June 2003 Report to the Congress, ''Variation and Innovation in Medicare,'' that, ''. . . LTCH patients have higher mortality rates and Medicare pays more for their care, compared with patients who do not use LTCHs'' (p. 71) and ''. . . total payments for LTCH users were 140 to 260 percent of payments for post-acute users in market areas without LTCHs (in 42 out of 44 DRG-severity levels). Death rates were higher for LTCH users compared with post-acute users in markets without LTCHs; this phenomenon may reflect unmeasured severity of illness'' (p. 85).

Although the report explicitly stated that MedPAC's findings were drawn from pre-PPS data, MedPAC noted that, ''. . . more research is needed to determine the role that LTCHs play for Medicare patients and to understand quality outcomes in this setting'' (p. 87).

The following year, in its June 2004 Report to Congress, ''New Approaches in Medicare,'' MedPAC provided a comprehensive examination of the LTCH universe based upon ''. . . both qualitative and quantitative approaches to answer our key questions regarding the role that LTCHs play, where patients in areas without LTCHs are treated, and the differences in Medicare payments and outcomes for patients who use LTCHs compared to those treated in other settings'' (p. 123). (For a detailed description of the methodology and data used in MedPAC's analysis, we refer readers to MedPAC's June 2004 Report to the Congress, p. 121 through 135). MedPAC's analysis resulted in the following findings:

- ''In the absence of LTCHs, clinically similar patients are principally treated in acute hospitals or in freestanding SNFs that are equipped to handle patients requiring a high level of care'' (p. 127).
- ''Medicare should use more precise criteria to ensure that LTCHs treat only appropriate patients. In general, beneficiaries treated in long-term care hospitals cost Medicare more than patients treated in alternative settings; however, if LTCH care is better targeted to those patients who appear to be most suitable for LTCH care, the costs to Medicare are more comparable'' (p. 127).
- ''. . . Criteria that limit the types of patients treated in LTCHs may help avoid some of the problems that may result from current payment incentives, growth of the LTCH industry and high payment rates'' (pp. 127 and 128).

Based on these and other findings, in that same report MedPAC made the following recommendation as ''Recommendation 5A'':

''The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.

- Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.
- Patient-level criteria should identify specific clinical characteristics and treatment modalities'' (p. 130).

MedPAC's 2004 recommendations for the development of patient-level criteria for LTCHs have driven discussion regarding CMS' policy on Medicare payments to LTCHs since that time. If LTCHs actually (and appropriately) treated a unique category of patients with specific clinical features, we could justify the larger payments (as compared to alternative care settings) being made under the LTCH PPS. At the same time, the MedPAC Report noted that there were only 350 LTCHs nationwide, and these LTCHs were not dispersed throughout the country in a manner that reflected Medicare beneficiary demographics. In areas without LTCHs, they found that clinically similar patients were treated in acute care hospitals and SNFs (pp. 124 and 125).

3. LTCHs in the Medicare Program

The concerns raised by MedPAC in 2004 have continued as the number of LTCHs has grown by more than 25 percent, from 350 in 2004 to approximately 440 in 2013. The above described geographic pattern appears to have continued with ''many LTCHs that have entered the Medicare program … located in markets where LTCHs already existed instead of in new markets with few or no LTCHs'' (MedPAC March 2012 Report to the Congress, ''Medicare Payment Policy,'' p. 261). For example, there are 38 LTCHs in Louisiana, where there is a beneficiary population of approximately 521,000, in New York State there are 4 LTCHs (all located in the New York City metropolitan area) with a beneficiary population of approximately 2,060,000. (We refer readers to the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2011.htm*, Table 2.5). Our 2012 data indicates that less than 2 percent of all Medicare beneficiaries who were hospitalized in CY 2010 were treated in LTCHs. Our 2013 data indicates that New Hampshire, Maine, and Vermont have no LTCHs and the following States have five or fewer LTCHs: Connecticut, Delaware, Hawaii, Iowa, Idaho, Kansas, Maryland, Minnesota, Montana, Nebraska, New Mexico, New York, Wisconsin, West Virginia, Wyoming, and the District of Columbia. Therefore, the number of LTCHs and their

geographic distribution suggest to us that LTCHs are only treating a small percentage of the patients that they have identified as their target population nationwide.

4. CMS' Research: The RTI Report

We awarded a multi-year contract to RTI (from 2004 through 2007) to identify and distinguish the role of LTCHs as Medicare providers. The name of the project was ''Long Term Care Hospital (LTCH) Payment System Refinement/Evaluation.''

RTI's reports generated under the LTCH Payment System Refinement/Evaluation project identified noteworthy trends that were developing in the LTCH industry since the introduction of the LTCH PPS, especially in terms of continued development of for-profit LTCHs, substantial increases in Medicare payments to LTCHs, and high LTCH profit margins for for-profit LTCHs under the LTCH PPS. (We refer readers to sections 1, 2, and 5 of the January 2007 ''LTCH Payment System Monitoring and Evaluation, Phase II Report,'' (hereinafter referred to as the RTI Report). In addition, RTI's findings suggested that LTCHs did not treat a ''unique'' type of patient (p. 129). As a result, RTI believed that it would be difficult to identify patient-level criteria that differentiated a LTCH patient from patients receiving care in other provider settings, particularly in general acute care hospitals due to the non-unique nature of the LTCH patient (p. 133).

RTI based these conclusions on an extensive and careful analysis of the Medicare populations served by LTCHs during 2004, and a comparison of these populations with those treated in other acute care settings, including IPPS, IRFs, IPFs, as well as those treated in less intensive settings such as SNFs. This analysis was further informed through the input from site visits and interviews with health professionals and hospitals. In addition, RTI contacted different stakeholder associations, including national hospital and quality review organizations, associations representing LTCHs (including one association that primarily represents non-profit LTCHs), and representatives of several of the larger LTCH chains. Through these organizations and others, RTI also sought input from physicians, nurses, and hospital administrators representing, in addition to LTCHs, acute care hospitals, IRFs, and ''high-acuity'' SNFs, that treat the ''type'' of patient who is treated in LTCHs and as inpatients in other provider settings. These individuals formed two RTI-convened technical expert panels (TEPs) that met in early 2007. Both TEPs generally agreed that LTCHs specialize in treating many of the types of patients they admit, and noted that having a high volume of these intensively ill patients was a driver for their successful outcomes. However, it was additionally noted that these medical services are also provided in general acute care hospitals, particularly in ICU step-down units. Therefore, while LTCHs may specialize in a select group of intensively ill patients, they were not the only providers to successfully provide these treatments. For more information on the TEPs, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26947 through 26948).

The Phase I and Phase II reports on RTI's research were summarized in our RY 2009 LTCH PPS proposed rule (73 FR 5374 through 5376) and have been posted under the ''RTI reports'' tab on the CMS Web site at: *http://www.cms.hhs.gov/LongTermCareHospitalPPS/02a_RTIReports.asp#TopOfPage*.

Of key significance in the discussion of the role of LTCHs under the Medicare program was our data-based assertion that we included in our RY 2008 LTCH PPS final rule that, ''[a]cross the United States, the over 3,700 acute care hospitals that discharge approximately 13 million Medicare beneficiaries treat the full range of medical issues including those that the commenters identify as LTCH cases,'' as compared to the 130,000 LTCH discharges that occurred during FY 2005. This Medicare data challenged the LTCH-industry commenters who believed that acute care hospitals paid under the IPPS do not and cannot deal with the medical conditions in which LTCHs specialize, and that patients remaining in general acute care hospitals rather than being transferred to LTCHs would receive ''substandard care'' (72 FR 26940). Several commenters argued that general acute care hospitals were ''just not capable'' of delivering the level of care required by typical LTCH patients. CMS responded to a number of these commenters by stating that, while ''[w]e do not question that many LTCHs have highly regarded reputations for their success in treating respiratory and ventilator cases (DRG 475) but . . . the 2004 MedPAR files indicate that [while] LTCHs treated 13,394 cases assigned to DRG 475 [which codes for respiratory system diagnosis requiring ventilator support], acute care hospitals treated 18,727 Medicare patients [assigned to DRG 475 and] an additional 7,072 [that qualified for high cost outliers (HCOs) who were assigned to] DRG 475. For DRG 88, chronic obstructive pulmonary disease (COPD), LTCHs treated 4,894 cases [and] acute care hospitals treated 37,523 cases. Data on other common DRGs treated in LTCHs as compared to the same DRG treated in acute care hospitals reflect a similar pattern, particularly among the DRGs that could fall into the broad category of ''medically complex'' patients'' (72 FR 26940 and 26041).

5. CMS' Report to Congress: Determining Medical Necessity and Appropriateness of Care for Medicare Long-Term Care Hospitals

In 2007, Congress imposed LTCH facility and patient-level criteria research and reporting obligations on the Secretary under section 114(b) of the Medicare and Medicaid State Children's Expansion Act of 2007 (MMSEA) (Pub. L. 110–173). The statute specified that:

''(1) In general.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a study on the establishment of national long-term care hospital facility and patient criteria for purposes of determining medical necessity, appropriateness of admission, and continued stay at, and discharge from, long-term care hospitals.

(2) Report.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), together with recommendations for such legislation and administrative actions, including timelines for implementation of patient criteria or other actions, as the Secretary determines appropriate.

(3) Considerations.—In conducting the study and preparing the report under this subsection, the Secretary shall consider—

(A) recommendations contained in a report to Congress by the Medicare Payment Advisory Commission in June 2004 for long-term care hospital-specific facility and patient criteria to ensure that patients admitted to long-term care hospitals are medically complex and appropriate to receive long-term care hospital services; and

(B) ongoing work by the Secretary to evaluate and determine the feasibility of such recommendations.''

In fulfillment of this statutory mandate, in 2008 CMS' Office of Research, Development, and Information (ORDI), which is now part of the Center for Medicare and Medicaid Innovation (the Innovation Center), awarded a contract to Kennell and Associates and their subcontractor RTI for additional analysis of data on Medicare payments and facility costs for

the treatment of similar patients in LTCHs and alternative providers, as well as an analysis of patient outcomes and the range of hospital-level care delivered in each setting. In accordance with section 114(b) of the MMSEA, Kennel/RTI was tasked with, among other things, considering MedPAC's June 2004 recommendations in their research, as well as ''. . . ongoing work by the Secretary to evaluate and determine the feasibility of such recommendations . . .'' as they researched and developed the 2011 Report to Congress (73 FR 26829).

In March 2011, we submitted our CMS Report to Congress, ''Determining Medical Necessity and Appropriateness of Care for Medicare Long Term Care Hospitals,'' (hereinafter referred to as the 2011 Report to Congress) on the development of LTCH patient and facility-level criteria as required by section 114(b) of the MMSEA. The MMSEA-mandated 2011 Report to Congress concluded that, ''. . . the Secretary does not recommend the development of additional patient and facility-level criteria for LTCHs at this time.'' The research offered the following support for the Secretary's conclusion:

- ''An examination of Medicare quality review contractors indicated that patients who are more appropriate for treatment at LTCHs than at other postacute care facilities have multiple comorbidities and require an intense level of care with frequent physician and nurse visits.
- The two most important factors in predicting LTCH admission are: (1) Proximity to an LTCH; that is, whether the beneficiary lived in a state where many LTCHs were available; and (2) severity of illness.
- There were no differences in average outcomes between episodes from areas that have high LTCH use and those that do not.
- For the most medically complex ventilator patients, Medicare payments were the same or lower, mortality was lower, and the chance of being discharged to home was higher than those remaining in acute care settings. However, among the least complex ventilator patients, Medicare payments were much higher, hospital stays were longer, and all other outcome measures were the same or worse for those referred to LTCHs versus those remaining in acute care settings. This finding supports previous research by MedPAC that LTCHs may provide beneficial and cost-effective services for a subset of complex patients, but not for all types of patients admitted to these hospitals.
- An LTCH admission was associated with a shorter length of stay in the general acute care hospital, on average, and controlling for a number of factors, including age, gender, number of comorbid conditions, and critical care use. * * * [A]t least for some patients, * * * LTCH care may be substituting for what would normally be provided in the later days of an acute care hospital stay.
- Between 40 to 45 percent of all LTCH admissions qualify for a payment reduction as a ''short-stay outlier''. This means that payments for these cases are reduced if the length of stay is substantially less than the average length of stay for a given LTCH–DRG. A high percentage of short-stay cases in a payment system designed for long-stay patients highlight the complexity in discerning which patients are appropriate for admissions to LTCHs.
- The RTI Technical Expert Panel (TEP) reached a consensus that LTCHs provide a service that is comparable to general acute step-down units and is not unique to LTCHs. Discussions with LTCH physicians and acute care hospital physicians practicing in areas that lack LTCHs confirmed that there is an overlap in the patient populations treated in LTCHs and in acute care. Critical care post-ICU patients whom LTCHs describe as their targeted population are treated throughout most of the country in acute care hospital step-down units.
- The TEP acknowledged that Medicare patients with respiratory conditions requiring mechanical ventilation comprise less than 15 percent of all LTCH patients. Thus, these patients insufficiently define which critically ill patients with complex medical conditions should be treated at LTCHs. It was not clear that any criteria can be developed which identifies patients who belong in a LTCH exclusively'' (2011 Report to Congress, pp. 6 and 7).

Regarding the establishment of facility-level criteria for LTCHs, the report noted the specific LTCH facility requirements established by section 114(a) of the MMSEA and stated that ''CMS believes that these facility-level standards should improve the quality of care at LTCHs and has no plans for additional facility-level standards. CMS acknowledges that while these new requirements represent new standards for care provision, facility-level standards will be of very limited value in determining the appropriateness of patients for LTCH care'' (2011 Report to Congress, pp. 10 and 11). The 2011 Report to Congress, which is entitled ''Determining Medical Necessity and Appropriateness of Care for Medicare Long-Term Care Hospitals,'' may be found on the CMS Web site at: *http://www.cms.gov/officeoflegislation/downloads/RTC-long-term-care-hospitals-final.pdf*. Our contractors' research findings can also be found in Appendix A of the 2011Report to Congress.

Research on the development of patient and facility-level criteria for LTCHs, as summarized above, indicated the absence of any empirical findings indicating an exclusive or unique ''LTCH patient.'' Rather, as noted in the 2011 Report to Congress, ''[f]ollowing the direction of MedPAC and the RTI TEP panels, CMS concurs with the view that LTCHs are appropriate providers for treating severely ill, but medically stable, patients with complex medical conditions. However, additional analysis of Medicare data across provider types is key in helping to formulate a clinically-based description of critically ill, medically complex patients'' (2011 Report to Congress, pp. 11 and 12).

The Secretary also noted that additional follow-up research that CMS was sponsoring would update and refine our understanding of Medicare LTCH patients and payments. This research effort was part of the Post-Acute Care Payment Reform Demonstration (PAC–PRD), a separate initiative and report to Congress mandated by section 5008 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171), and collected standardized patient assessment information using the Continuity Assessment Record and Evaluation (CARE) tool, which had been designed to be administered to patients in all acute and post acute care settings with the goal of developing consistent measures for case-mix adjustment. The 2011 Report to Congress indicated that, ''[o]going research using the CARE tool should facilitate CMS' efforts to empirically define types of chronic, complex medical conditions that currently receive treatment in both general acute care hospitals and LTCHs.'' To this end, the 2011 Report to Congress noted, ''CMS is currently funding contract research to use the CARE tool to collect suitable patient-level clinical data to better identify chronic, critically ill patients. CMS is also currently funding research to develop payment models that would pay for these patients' care reasonably and appropriately in LTCHs or any other site of care'' (2011 Report to Congress, pp. 12 and 13).

The data collected using the CARE tool from the PAC–PRD project represent a significant new benchmark

in capturing clinical patient-level data to measure outcomes, quality of care, and performance at LTCHs and other provider settings treating similar conditions. Previously, claims data was the only clinical information available to inform RTI's LTCH research from 2004 through 2007. The data collected using the CARE tool has allowed Kennell/RTI's follow-up research to evaluate ''types of chronically ill patients with complex medical conditions, regardless of provider setting'' and ''to measure outcomes, quality of care and performance at LTCHs and other providers treating similar clinical conditions'' (2011 Report to Congress, p. 12).

For additional information on the PAC–PRD report to Congress and for the CARE tool, we refer readers to: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Flood_PACPRD_RTC_CMS_Report_Jan_2012.pdf* and *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/GAGE_PACPRD_RTC_Supp_Materials_May_2011.pdf*.

In response to the established need for additional research on the key findings of the MMSEA-mandated Report to Congress, CMS extended its research contract with Kennell/RTI to utilize the clinical data provided by the CARE tool, as described above, and to examine payment issues associated with chronically critically ill and medically complex patients with long-term hospital needs. Kennell/RTI was also tasked with developing a robust clinical definition of the subgroup of chronically critically ill and medically complex patients identified as appropriate for treatment in both LTCHs and general acute care hospitals in order to allow for the evaluation of appropriate payment policies for the various settings in which patients are treated. (We refer readers to Appendix A of the 2011 Report to Congress, p. 79 through 86, for details on this follow-up research under the ''Medical Necessity and Appropriateness of Care'' contract for the ''Long Term Care Hospitals and the Chronically Critically Ill Population Payment Recommendations'' (CCIP–PR).)

These additional recent research initiatives were focused on evaluations of clinical data on chronically critically ill Medicare beneficiaries. The variations in provider costs and the resulting Medicare payment differentials for treating these patients in different provider settings were also evaluated.

6. Current Patterns in LTCHs

Kennel/RTI's follow-up research to the 2011 Report to Congress studied trends in LTCH utilization based on 100 percent of the MedPAR data files for LTCH claims for 2004, 2006, 2008, and 2010 provided the context and the foundation for the framework discussed below. This work indicated the following facts about LTCHs:

- LTCHs and LTCH use has expanded significantly.
  - Between calendar year 2004 and 2010: number of LTCHs grew from 369 to 443 (+20%)
  - The number of LTCH discharges grew from 125,000 to 141,000 (+13%)
  - Medicare LTCH–PPS payments grew from $3.7 billion to $5.2 billion (+41%)
- LTCH patients are becoming more complex:
  - More complex LTC–DRG types being admitted to LTCHs in terms of the relative value weights of the MS–LTC–DRGs used.
  - Higher mix of severity within LTC DRGs in terms of the percent of patients with an MCC level of comorbidity status.
  - Higher mix of severity within referral IPPS DRGs
  - Increasing proportion of patients admitted with critical care in their prior IPPS stay
  - Taken together, the evidence suggests real change in case mix, over and above any behavioral changes in coding
  - It should be noted that these trends began well before the 2008 implementation of the MS–LTC–DRG system.
- LTCH use is associated with *substantial* increases in:
  - Combined IPPS + LTCH PPS payments
  - Of combined IPPS + LTCH PPS costs
  - Total episode inpatient days

Furthermore, RTI found that respiratory conditions (including mechanical ventilation, respiratory infections, pulmonary edema and respiratory failure), increased as a share of LTCH admissions from less than 20 percent in 2004 to almost 30 percent in 2010. The share of admissions for septicemia more than doubled, and the percentage of admissions for osteomyelitis nearly doubled. Other less complex conditions that accounted for a relatively large share of LTCH claims in CY 2004 declined rapidly. For example, the percentage of LTCH admissions for degenerative nervous system disorders and rehabilitation fell by more than half and the percentage of admissions for musculoskeletal and other types of aftercare fell by half. The number and percentage of patients with heart failure and shock and with COPD also declined. The percentage of admissions for wound and skin conditions (including cellulitis, skin graft and debridement, and wound debridement) did not change. Over this period, Medicare data indicated that LTCH case-mix has become more concentrated in complex respiratory care and treatment of certain types of complex infections.

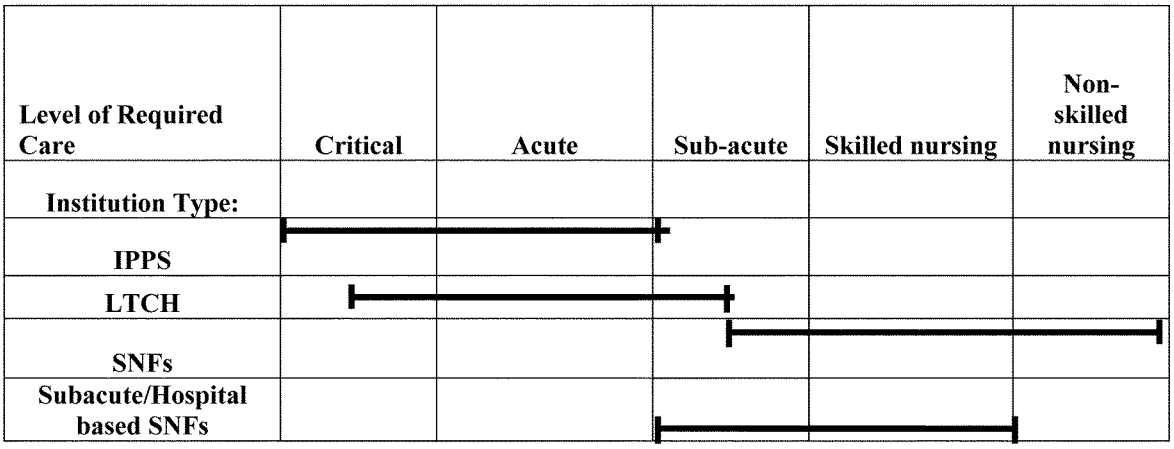
Medicare data also reveals changes in levels of severity both overall and within the conditions (or base DRG families) of LTCH admissions since the start of the LTCH PPS. The percentage of admissions assigned to MS–LTC–DRGs with major complications or comorbidities (MCCs) increased from 37 percent to 61 percent over the study period, and the percentage of patients assigned to any of the single-severity ventilator DRGs increased from 12 percent to 16 percent over the study period. Complications or comorbidities (CCs) that did not rise to the level of MCCs had accounted for 39 percent of LTCH admissions in CY 2004, but only 20 percent in CY 2010. MS–LTC–DRGs with no CCs fell from 9 percent to 2 percent. Finally, Kennell/RTI found that the shift toward higher severity levels is evident not only within more complex conditions where the patient load is increasing, but also within the less complex conditions where the relative patient load has been declining. In summary, since the implementation of the LTCH PPS in FY 2003 there have been significant changes in LTCH case-mix and severity within case-mix.

A comparison of MedPAR data from CY 2006 to CY 2010 also indicated that an increasing proportion of the patients transferred to LTCHs had received critical care services at an IPPS hospital immediately prior to their LTCH admission. The number of such individuals rose from 54.9 percent to 58.5 percent of transfers. The number of individuals with at least one week of critical care in an IPPS hospital immediately prior to their LTCH admission also rose from 36.2 percent to 38.8 percent of transfers; and the number of individuals who were discharged directly from critical care to a LTCH (having spent no time in general hospital routine units) rose from 25.2 percent to 30.3 percent of transfers.

As a result, Kennell/RTI reported that, for purposes of understanding the most efficient use of Medicare resources in LTCHs and other provider settings for high acuity patients, with a focus on LTCHs, a primary step is an analysis of

the spectrum of patients in LTCHs, with the chronically critically ill at one end, who overlap with hospital critical care and account for anywhere from a third to a half of the LTCH Medicare admissions continuum, and patients who may be approaching sub-acute levels of need at the other end. Kennell/RTI found that the potentially sub-acute level of care patients could account for as much as 15 to 20 percent of LTCH Medicare admissions.

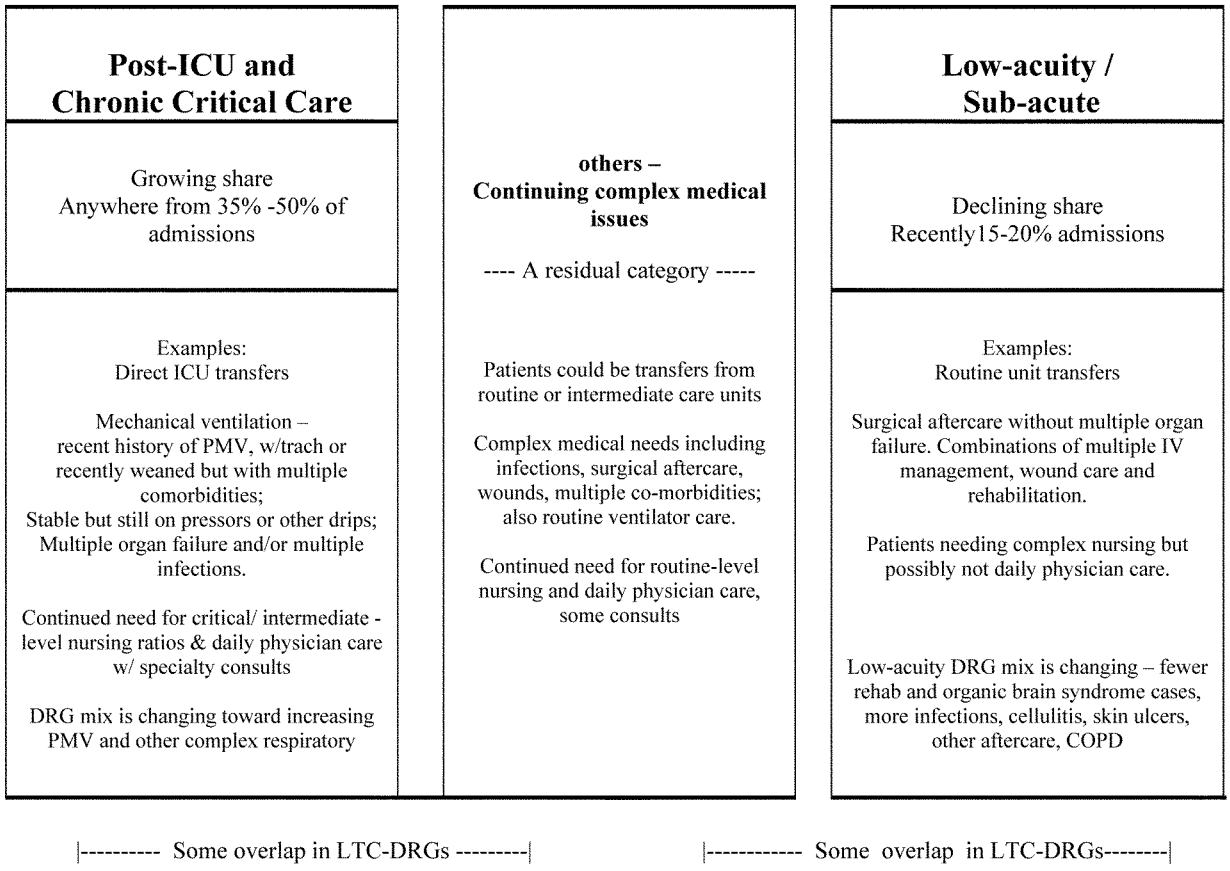
Range of Levels of Required Care and Overlap of Institutions Providing That Care



The chart above is useful for visualizing the observed patient acuity levels associated with various treatment sites under Medicare. It should be noted that these ranges do not necessarily represent desired or even appropriate levels of care within a setting.

While the data generally revealed an acuity continuum, RTI also developed three ''categories'' of patients in order to simplify presentation of their findings. The chart below summarizes RTI's findings for these three acuity groups for LTCH patients treated in FYs 2004, 2006, 2008, and 2010:

Three LTCH Populations



7. Identification of Chronically Critically Ill/Medically Complex (CCI/MC) Patients

As noted above, CMS extended its research contract with Kennell/RTI following CMS' issuance of the 2011 Report to Congress in order to develop a robust definition of the group of patients who our research confirmed could be appropriate for treatment at LTCHs and higher payments under the LTCH PPS—that is, those who are chronically critically ill and medically complex (CCI/MC). We also tasked RTI in the CCIP–PR contract with the examination of any payment issues across provider settings that might be associated with CCI/MC patients with long-term hospital treatment needs.

The diagram below (which we discuss further below) illustrates the steps taken by Kennell/RTI to determine and refine the CCI/MC definition.

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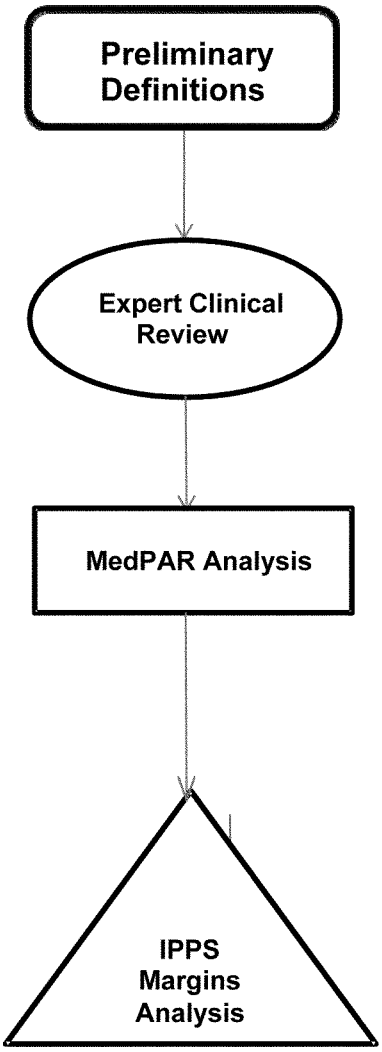

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The first step illustrated in the chart above represents Kennell/RTI's further evaluation of the materials in Appendix A of the 2011 Report to Congress. Next, Kennel/RTI brought in several clinical consultants to provide feedback on those initial definitions. These experts suggested refinements to the clinical characteristics that could be used to describe CCI/MC patients in our request for RTI to examine clinical factors/conditions that are related to very long IPPS hospital or IPPS hospital plus LTCH treatment episodes, as well as factors related to long ICU stays that had not been included in the initial definitions found in Appendix A of the Phase II Report. We were particularly interested in identifying patients with certain conditions that regularly exceeded the average length of stay for MS–DRGs or that routinely became IPPS outliers.

In general, these clinical consultants agreed that the initial definitions provided in Appendix A of the Phase II Report gave an appropriate range of clinical conditions that could be used to define CCI/MC. However, they suggested some specific changes as well which, if accepted, would lead us to consider changes to some of the clinical conditions that we would want to include in our own eventual definition of CCI/MC. For example, based on feedback from the clinical consultants, we would add stroke, brain hemorrhage, and traumatic brain injury to the list of organ failure codes. We would also add leukemia and lymphoma as organ failures. Other suggestions would lead us to remove codes from the organ failure category. For example, we would remove chronic kidney disease and early stage pressure ulcers.

To confirm whether the changes in clinical characteristics recommended by the clinical consultants would identify long-staying and high-cost patients, Kennell/RTI used a 2009 MedPAR data set to analyze the clinical consultants' recommendations related to episode lengths of stay, costs, and prevalence of the condition. This 2009 data set included index IPPS stays and additional institutional stays during the episode of care. We found that the data supported the clinical suggestions, and that patients diagnosed with lymphoma and leukemia did have long median general acute care hospital lengths of stay. Patients with Stage III and IV pressure ulcers and congestive heart failure (unspecified) were included in the data, and the MedPAR analysis confirmed the inclusion of primary and secondary diagnoses of stroke, brain hemorrhage, and traumatic brain injury.

Kennell/RTI also analyzed margins for Medicare payments to IPPS hospitals for those cases that met the preliminary definitions, including those with wounds, sepsis, multiple organ failure, and prolonged mechanical ventilation. As a result of these and additional evaluations, preliminary findings from Kennell/RTI's project ''Chronically Critically Ill Population Payment Reform (CCIP–PR)'' identified CCI/MC patients generally as:

- Requiring extended intensive care unit or critical care unit (ICU or CCU) stays in IPPS hospitals;
- Having high Medicare payments; and
- Having diagnoses including such factors as the presence of sepsis, prolonged mechanical ventilation (PMV), and multiple organ failure.

Specifically, Kennell/RTI's research defines CCI/MC patients as representing a population that is clinically variable in the presentation of its underlying disorders, yet definable in its final patterns of intensive service needs.

MedPAC came to similar conclusions in their March 2012 Report to Congress. In that report, they highlighted a definition of chronically critically ill patients, which was originally proposed by Nierman and Nelson in 2002, that noted ''. . . the chronically critically ill patient exhibited metabolic, endocrine, physiologic, and immunologic abnormalities that resulted in profound debilitation and often ongoing respiratory failure, abnormalities that slowed or precluded recovery from a wide range of acute forms of medical, surgical, and neurologic critical illness'' (pp. 273 and 274).

Kennell/RTI's follow-up research findings confirmed that a distinction can be drawn between chronically critically ill patients and patients who may need extended acute care, but do not require critical care. The medically complex (MC) patients are generally medically compromised (due to, for example, multiple comorbidities) and they may have prolonged care needs for surgical aftercare, wounds, or infections, but do not require long periods of mechanical ventilation and do not otherwise fit Kennell/RTI's understanding of the clinical profile of CCI/MC patients. These patients may require hospitalization over several weeks or even months due to medical complexities in their care protocol that require acute-level nursing, but they have either not needed intensive-care nursing or have progressed from intensive to less intensive nursing care needs. However, both groups have a need for continued hospital-level care that can be met either through continued treatment in the initial acute care hospital or by a transfer to a LTCH or other provider setting. As noted, our research has indicated that the Medicare

costs of delivering care to such patients in the various settings that could meet their treatment needs varies widely. Moreover, our most recent Kennell/RTI research findings indicate that, although LTCHs are admitting an increasing number of chronically critically ill patients and an increasing number of patients with prior critical care stays in the general acute care hospital, the majority of LTCH cases during the years evaluated do not fit the operational definition of CCI/MC patients or even medically complex, high acuity patients.

8. LTCH PPS Payments for CCI/MC Patients

In summary, research sponsored by CMS under the original RTI contract (awarded from 2004 through 2007), findings from the PAC–PRD Report to Congress, the 2011 Report to Congress, and Kennell/RTI's follow-up research under the CIPP–PR study, as well as findings in historic and recent MedPAC Reports to Congress, have led us to believe that there are specific factors that can be used to identify the CCI/MC patient population, which can, in turn, be used to provide a robust definition for the core group of patients that we believe are appropriate for treatment at LTCHs and payment under the LTCH PPS. Furthermore, as CMS and its contractors evaluated Medicare claims and utilized the information derived from the application of the CARE tool across treatment settings to further analyze the care needs of this unique group, we have determined that our CCI/MC definition would capture a distinct subset of patients with consistent and significant negative margins when treated by general acute care hospitals paid under the Medicare IPPS—a phenomenon that generally does not appear to be evident for other long-stay medically complex cases that are treated in the IPPS hospital setting.

As noted above, CMS wants to ensure that LTCHs treat the most appropriate patients given the comparatively high payments in this provider setting. While the original MedPAC recommendation that we develop LTCH-specific patient-level criteria has evolved somewhat over time, we believe we can identify CCI/MC patients as potentially appropriate for treatment in the LTCH setting. MedPAC's and CMS' data analyses have indicated that financial forces in the IPPS context may be encouraging the transfer of these and other high-cost cases to LTCHs, but the non-CCI/MC patients may not receive cost-effective care in the LTCH setting. Therefore, we are outlining potential revisions of the LTCH PPS that would be aimed at encouraging the LTCH industry to admit patients fitting the CCI/MC profile to ensure that such patients frame LTCHs' ''core'' patient populations. We believe that the potential revisions to the LTCH PPS, which are described below would encourage LTCHs to refocus their admissions policies on serving medically stable but high-acuity patients.

The research suggests that, for purposes of this discussion, we consider CCI/MC patients to be those with the specific characteristics described below. A system that would identify CCI/MC patients would facilitate limiting the full LTCH PPS payment to patients who meet this definition of CCI/MC while they were in an IPPS hospital inpatient setting if they are subsequently directly admitted to a LTCH. CCI/MC status would be used to identify patients as they are discharged from an IPPS hospital and then transferred to a LTCH. We could also apply an adjustment to LTCH payments for non-CCI/MC patients, that is, patients who by definition would not be most appropriate for treatment in a LTCH. Payment for non-CCI/MC patients would be made at an ''IPPS comparable amount,'' that is, an amount comparable to what would have been paid under the IPPS calculated as a per diem rate with total payments capped at the full IPPS MS–DRG payment rate.

The research suggests that a patient would be identified as a CCI/MC patient in the IPPS setting based on having one or more of the five clinical factors listed in the table below, combined with a stay of 8 or more days in an ICU/CCU at an IPPS hospital. The CCI/MC patient definition would be used to identify patients as they are discharged from an IPPS hospital and then transferred to a LTCH.

FIVE CRITICALLY ILL/MEDICALLY COMPLEX STATUS CLINICAL FACTORS

Prolonged Mechanical Ventilation (PMV).
Tracheotomy.
Multiple Organ Failure/Stroke/Intercerebral Hemorrhage/TBI.
Sepsis and Other Severe Infections.
Severe Wounds.

The CCI/MC patient population discussed above have been shown to have intensive service needs, high costs, and negative margins in IPPS hospitals. In addition, these patients typically have a predictable and consistent need for extended hospital-level care that can be met either from continued stays in the initial IPPS hospital in a step-down unit after ICU or CCU treatment, or through transfer to a LTCH.

When the LTCH PPS was implemented in FY 2003, length of patient stay was considered a proxy measure for resource use. MedPAC's early research findings, subsequently confirmed by our researchers, however, provided clear evidence that without knowing the mix of routine or critical care days, length of stay was not a reliable proxy for patient acuity. As noted above, Medicare data indicates that LTCHs treat many patients with very long episode stays that did not meet the CCI/MC criteria. Under section 1886(d)(1)(B)(iv)(I) of the Act, a LTCH is an acute care hospital with an average length of stay of greater than 25 days. Therefore, under current law, an LTCH may treat even short-stay, non-critically ill patients as long as it maintains an average length of stay that exceeds 25 days. However, under this framework an adjusted LTCH PPS payment equal to the ''IPPS-comparable'' amount could be paid to a LTCH for those patients admitted to the LTCH without meeting the CCI/MC designation—that is, an amount comparable to what would have been paid under the IPPS calculated as a per diem rate with total payments capped at the full IPPS MS–DRG payment rate.

We anticipate that if the payment policy is revised consistent with the framework discussed above, the industry could make adjustments to their admission and referral practices, and the mix of patients admitted to LTCHs would change significantly. Furthermore, our data discussed above detailing significant changes in LTCH admission practices since the start of the LTCH PPS would appear to indicate that LTCHs are already slowly revising their practices by admitting more critically ill patients. We are inviting public comments on whether such a policy could obviate the need for the ''25-percent threshold payment adjustment policy.'' In the future, if LTCHs begin to focus on treating CCI/MC patients, based on our research we believe that the Medicare program would be purchasing specialized and cost-effective services when making payment for these defined CCI/MC patients.

We believe that the potential policy changes discussed above are consistent with a significant body of research, which identifies the CCI/MC patient criteria as a useful indicator of an appropriate LTCH admission. Furthermore the CCI/MC criteria would appear to identify the patients that LTCHs have asserted in their discussions with CMS that they are best equipped to treat.

Although Kennell/RTI's research is not yet completed, we want to note that we believe that the findings from the LTCH research over the past decade, culminating in the payment policy discussion we have outlined, is consistent with MedPAC's June 2004 Report to Congress' recommendations. As discussed earlier, in that report the Commission recommended that CMS develop LTCH criteria that would result in identifying those patients whose conditions would justify Medicare's payments under the LTCH PPS and ultimately dissuade LTCHs from treating those patients who did not meet the criteria. As described above, the advent of the CARE tool significantly extended the depth and range of our prior research initiatives. By utilizing data from the CARE tool, in addition to the research methodology specified above, to identify the CCI/MC population, we believe that we have established a robust set of patient-level criteria for Medicare payment in LTCHs and have responded to MedPAC's concerns. Finally, we note that at both its January 11, 2013 and April 5, 2013 public meetings MedPAC discussed three ''policy options'' to ''improve payment for chronically ill beneficiaries'' that are also based in part on the use of ICU services as a defining characteristic of these CCI/MC patients. The first option offered by MedPAC would ''remove the LTCH designation and pay for cases under a modified IPPS, which would include changes to the current IPPS high-cost outlier policy. The IPPS modifications would improve payment accuracy for very costly CCI patients.'' A second option builds on the first by also breaking out CCI patients into separate MS–DRGs with higher payment relative weights. The third option would bundle expected post acute care costs into the new CCI MS–DRGs so that the hospital would be responsible for associated LTCH or SNF care for CCI/MC patients. MedPAC noted that more details of these options would be presented in ''the coming months.'' We will continue to analyze MedPAC's work and future recommendations. (Additional information on these public meetings, including transcripts, are available on MedPAC's Web site: *http://www.medpac.gov/meetings.cfm*.)

We will post final reports on Kennell/RTI's follow-up research on the CMS Web site as soon as they are completed. As previously noted, we are eager to receive public comments regarding this discussion of the research and the development of a patient criteria-based payment adjustment under the LTCH PPS as well as on the impact of such a proposal on hospital markets in advance of a policy proposal that we are expecting to include in the FY 2015 IPPS/LTCH PPS proposed rule in the spring of 2014.

IX. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. CMS has worked with relevant stakeholders to define measures of quality 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, and, increasingly, outcomes.

CMS has implemented quality reporting programs for multiple settings of care, 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 (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,
- Hospices, under the Hospice Quality Reporting Program.

CMS has also implemented an end-stage renal disease quality improvement program (76 FR 628 through 646) that links 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 burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, so that the electronic collection of performance information is part of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructural development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that in the near future, automatic collection and reporting of data elements for many measures 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 reporting of data for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We have also implemented a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. In 2011, we issued the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We adopted additional policies for the Hospital VBP Program in section IV.B. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660), in section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547) and in section VIII.C. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614). Under the Hospital VBP Program, hospitals will receive value-based incentive payments if they meet performance standards with respect to measures 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 of the Hospital VBP Program. Section 1886(o)(2)(B)(i)(I) of the Act states that for FY 2013, the selected measures for the Hospital VBP Program must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), surgical care, as measured by the Surgical Care Improvement Project (SCIP), and Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (or any successor HHS plan). Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital VBP Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

The Hospital IQR Program is linked with the Hospital VBP Program because the measures and reporting infrastructure for both 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 instead of merely volume. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), we applied the following principles for the development and use of measures and scoring methodologies:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of this effort, we will continuously seek to align our measures with the adoption of e-specified measures, and reporting of quality data via Certified Electronic Health Record Technology (CEHRT), so the electronic collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized 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 program established by section 3008 of the Affordable Care Act, the HAC Reduction Program, creates a payment adjustment resulting in payment reductions for the lowest performing hospitals based on their rates of HACs. Proposals for the HAC Reduction Program are included in section V.I. of the preamble of this proposed rule.

Although we intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers, we also view programs that could potentially affect a hospital's Medicaid payment as separate from programs that could potentially affect a hospital's Medicare payment.

In the preamble of this proposed rule, we are proposing changes to the following Medicare quality reporting systems:

- In section V.H., the Hospital VBP Program.
- In section IX.A., the Hospital IQR Program.
- In section IX.B., the PCHQR Program.
- In section IX.C., the LTCHQR Program.
- In section IX.D., the IPFQR Program.

In addition, in section IX.E. of the preamble of this proposed rule, we are proposing changes to the Electronic Health Record Incentive Program and meaningful use.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of Measures Adopted for 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 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555) for the measures we have adopted for the Hospital IQR measure set through FY 2016.

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 *https://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. We will provide ICD–9 to ICD–10 crosswalks for the measure specifications in the manual for preview and comment in the July 2013 manual release.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual, which is available at the HCAHPS On-Line 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). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process. 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 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, medication updates for categories of medications, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy under which we will use a subregulatory process to make non-substantive updates to NQF-endorsed measures used for the Hospital IQR Program. With respect to what constitutes substantive versus nonsubstantive changes, we expect to make this determination on a case-by-case basis. Examples of non-substantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also will post the updates on the QualityNet Web site at *https://www.QualityNet.org*. We will provide sufficient lead time for hospitals to implement the changes where changes to the data collection systems would be necessary.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the Hospital IQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. The quality measure SCIP Infection 4, Controlled 6AM Glucose for Cardiac Surgery Patients (NQF #300), is an example of a measure that has undergone extensive changes as a result of the NQF maintenance process. The specifications have substantively changed and we are proposing to adopt these changes in this proposed rule. As we discuss below, the NQF Steering Committee voted to change the measure from controlled glucose at 6AM to controlled glucose 18–24 hours post-surgery for cardiac surgery patients. The specifications also require corrective action to be documented if a post-operative glucose is over 180mg/dl. The specifications for the proposed updated measure can be found at: *http://www.qualityforum.org*.

We believe that this policy adequately balances our need to incorporate non-substantive NQF updates to NQF–endorsed Hospital IQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital IQR Program.

c. Proposed Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, 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 are proposing, for the FY 2014 Hospital IQR Program and subsequent years, to continue 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.hospitalcompare.medicare.gov*, and/or the interactive *https://data.medicare.gov* Web site, after a 30-day 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. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey, structural measures, Emergency Department Throughput timing measures, hospital acquired condition measures, immunization measures, and hospital acquired infection measures, all of which are featured on the *Hospital Compare* Web site.

However, information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations for inclusion on *Hospital Compare* may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as *http://www.cms.hhs.gov/HospitalQualityInits/* or *https://data.medicare.gov*. Publicly reporting the information in this manner, although not on the *Hospital Compare* Web site, allows CMS to meet the requirement under section 1886(b)(3)(B)(viii)(VII) of the Act for establishing procedures to make information regarding measures submitted under the Hospital IQR Program available to the public following a preview period. In such circumstances, affected parties are

notified via CMS listservs, CMS email blasts and memorandums, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53507 through 53508), we removed five Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs). We did so noting that four of these indicators were part of the AHRQ PSI–90 measure, and that this information could be made publically available in the future in addition to the PSI–90 composite measure results that we currently make publically available. We recently received feedback from consumer advocacy groups and large purchasers that data on the individual PSI indicators that are part of the PSI–90 composite measure are highly relevant to consumers, and not publically reporting them would be a disservice to consumers of healthcare. Therefore, we are proposing to make publicly available hospital level data for the PSI indicators that are part of the PSI–90 composite in addition to the composite results. We invite public comment on this proposal.

We also invite public comment on what additional quality measures and information featured on *Hospital Compare* may be highly relevant to patients and other consumers of healthcare, and how we may better display this information on the *Hospital Compare* Web site. One option we have considered is aggregating measures in a graphical display, such as star ratings.

2. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

Generally, we retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when they are removed or replaced as indicated. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53505 through 53506) for a discussion of the considerations we use in removing (formerly referred to as retiring) previously adopted Hospital IQR Program measures.

b. Hospital IQR Program Measures Removed in Previous Rulemaking

In previous rulemakings, we have removed numerous Hospital IQR Program quality measures, including:

- PN–1: Oxygenation Assessment for Pneumonia, a ''topped-out'' measure, because measures with very high performance among hospitals present little opportunity for improvement and do not provide meaningful distinctions in performance for consumers (73 FR 48604).
- AMI–6: Beta Blocker at Arrival measure from the Hospital IQR Program because it no longer ''represent[ed] the best clinical practice,'' as required under section 1886(b)(3)(B)(viii)(VI) of the Act. We stated that when there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, it is appropriate for CMS to take immediate action to remove a measure from the Hospital IQR Program and not wait for the annual rulemaking cycle. Therefore, we adopted the policy (74 FR 43864 and 43865) that we would promptly remove such a measure, confirm the removal in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly remove measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos, email notification, and QualityNet Web site postings. To this end, we confirmed the removal of the AMI–6 measure in the FY 2010 IPPS/LTCH PPS rulemaking cycle after immediate suspension because the measure posed patient safety risks.
- Mortality for Selected Procedures Composite measure because the measure is not considered suitable for purposes of comparative reporting by the measure developer (75 FR 50186).
- Three adult smoking cessation measures: AMI–4: Adult Smoking Cessation Advice/Counselling; HF–4: Adult Smoking Cessation Advice/Counselling; and PN–4: Adult Smoking Cessation Advice/Counselling, because these measures are ''topped-out'' and no longer NQF-endorsed (76 FR 51611).
- PN–5c: Timing of Receipt of Initial Antibiotic Following Hospital Arrival measure out of concerns that the continued collection of this measure might lead to the unintended consequence of antibiotic overuse (76 FR 51611).
- 17 measures set out below (77 FR 53506 through 53509)

Topic	17 Measures removed from hospital IQR program measure set for the FY 2015 payment determination and subsequent years
Surgical Care Improvement Project (SCIP) Measure	
	• SCIP INF–VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered *
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	• PSI 06: Iatrogenic pneumothorax, adult ** • PSI 11: Post Operative Respiratory Failure ** • PSI 12: Post Operative PE or DVT ** • PSI 14: Postoperative wound dehiscence ** • PSI 15: Accidental puncture or laceration ** • IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) ** • IQI 19: Hip fracture mortality rate ** • IQI 91: Mortality for selected medical conditions (composite) **
Hospital Acquired Condition Measures	
	• Foreign Object Retained After Surgery ** • Air Embolism ** • Blood Incompatibility ** • Pressure Ulcer Stages III & IV ** • Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock) ** • Vascular Catheter-Associated Infection ** • Catheter-Associated Urinary Tract Infection (UTI) ** • Manifestations of Poor Glycemic Control **

* Chart-abstracted measure.

** Claims-based measure.

c. Proposed Removal of Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

As we move toward more outcome-related measures, we have considered the removal of additional measures using our stated removal criteria. We are proposing to remove 8 measures from the Hospital IQR Program. Three measures are chart-abstracted (one pneumonia measure, one heart failure measure, and one immunization measure), and one is a structural measure (Systematic Clinical Database Registry for Stroke Care). We are are also proposing to remove 4 additional chart-abstracted measures from the Hospital IQR Program because they were either recommended for removal by the MAP during the pre-rulemaking process or are considered ''topped out.''

(1) Proposed Removal of PN–3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital Measure

In the FY 2007 IPPS final rule, we adopted PN–3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital. We are proposing to remove this measure based on several considerations. First, the measure is no longer NQF-endorsed. Second, the MAP recommended removal of the measure from the Hospital IQR Program in a February 2013 pre-rulemaking report that made recommendations on measures under consideration by HHS. The MAP believed the measure was topped-out with no room for improvement. Third, the measure lacks an adequate association between processes of care and patient outcomes. Accordingly, since there is only limited data showing impact from drawing blood cultures prior to administering antibiotics and to address concerns of overuse of blood cultures, we are proposing to remove PN–3b from the Hospital IQR Program.

(2) Proposed Removal of HF–1: Discharge Instructions Measure

In the FY 2007 IPPS final rule we adopted HF–1: Discharge Instructions. We are proposing to remove this measure based on several considerations. First, the measure is no longer NQF-endorsed. Second, the MAP recommended removal of the measure from the Hospital IQR Program in a February 2013 pre-rulemaking report that made recommendations on measures under consideration by HHS. The MAP was concerned because research showed a weak correlation between this measure and patient outcomes. Third, while we consider discharge instructions an important aspect of patient care, we face a challenge in validating the efficacy of the information received with this measure. Therefore, we are proposing to remove HF–1 from the Hospital IQR Program.

(3) Proposed Removal of IMM–1: Immunization for Pneumonia Measure

We adopted IMM–1: Immunization for Pneumonia for the Hospital IQR Program for the FY 2014 payment determination with data collection beginning with January 1, 2012 discharges. We are proposing to remove this measure based on the following consideration. In October of 2012, the Advisory Committee on Immunization Practices (ACIP) released new guidelines on the administration of pneumococcal vaccination for various populations. Because IMM–1 was already required as part of the Hospital IQR Program before the new guidelines were published, we cannot feasibly implement the measure to incorporate the potential iterations of the new guidelines. We believe that maintaining the measure in the Hospital IQR Program during this period of rapid guideline changes would detract from hospitals efforts to administer vaccines appropriately.

We emphasize that, despite the removal of IMM–1 from the Hospital IQR Program, we expect hospitals to continue to keep up-to-date with the vaccination recommendations for various populations.

(4) Proposed Removal of the Systematic Clinical Database Registry for Stroke Care Measure

We adopted the Systematic Clinical Database Registry for Stroke Care measure for the Hospital IQR Program for the FY 2013 payment determination beginning with January 1, 2011 discharges. We are proposing to remove this measure based on the following consideration. Since the adoption of this structural measure, we have adopted a Stroke measure set beginning with January 1, 2013 discharges. We believe that the Stroke measure set will provide more meaningful and detailed information regarding how well stroke care is being managed in a hospital setting than the current structural measure, which consists of a general yes/no response.

(5) Proposed Removal of Four Additional Chart-Abstracted Measures

We are also proposing to remove four chart-abstracted measures from the Hospital IQR Program because these measures were either recommended for removal by the MAP during the pre-rulemaking process or are considered ''topped out.''

- AMI–2: Aspirin prescribed at discharge
- AMI–10: Statin prescribed at discharge
- HF–3: ACEI or ARB for LVSD
- SCIP-Inf–10: Surgery Patients with perioperative temperature management

We invite public comment on our proposal to remove these measures.

Topic	Proposed removal of hospital IQR program measures for the FY 2016 payment determination and subsequent years
Acute Myocardial Infarction	
	• AMI–2 Aspirin prescribed at discharge. • AMI–10 Statin prescribed at discharge.
Pneumonia	
	• PN–3b Blood culture performed in the emergency department prior to first antibiotic received in hospital.
Heart Failure	
	• HF–1 Discharge instructions. • HF–3 ACEI or ARB for LVSD.

Topic	Proposed removal of hospital IQR program measures for the FY 2016 payment determination and subsequent years
Surgical Care Improvement Project	
	• SCIP–Inf–10 Surgery patients with perioperative temperature management.
Immunization	
	• IMM–1 Immunization for pneumonia.
Structural Measure	
	• Participation in a systematic clinical database registry for stroke care.

d. Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51611), we suspended data collection for four measures beginning with January 1, 2012 discharges, affecting the FY 2014 payment determination and subsequent years.

Topic	Hospital IQR program measures suspended for the FY 2014 payment determination and subsequent years
Acute Myocardial Infarction (AMI)	
	• AMI–1 Aspirin at arrival. • AMI–3 ACEI/ARB for left ventricular systolic dysfunction. • AMI–5 Beta-blocker prescribed at discharge.
Surgical Care Improvement Project (SCIP)	
	• SCIP INF–6 Appropriate Hair Removal.

We suspended, rather than removed, these measures, despite having evidence that these measures may be topped-out (that is, their performance is uniformly high nationwide, with little variability among hospitals) because we believe that the processes assessed by these measures are tied to better patient outcomes, and that permanent removal of the measures from the Hospital IQR Program may result in declines in performance and, therefore, worse outcomes. Therefore, we decided not to remove these measures from the Hospital IQR Program. The suspension of data collection for these four measures will be continued unless we have evidence that performance on the measures is in danger of declining. Should we determine that hospital adherence to these practices has unacceptably declined, we would resume data collection using the same form and manner and on the same quarterly schedule that we finalize for these and other chart abstracted measures, providing at least 3 months of notice prior to resuming data collection. Hospitals would be notified of this via CMS listservs, CMS email blasts, national provider calls, and QualityNet announcements. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before resuming data collection of these four measures.

3. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

For the purpose of streamlining the rulemaking process, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), we finalized our policy that 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.

4. Additional Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program

We 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 measures under the Hospital IQR Program and our policy, beginning with the FY 2013, to use one calendar year of data for chart-abstracted measures for payment determinations.

5. Proposed Changes to Hospital IQR Program Measures Previously Adopted for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

a. Previously Adopted Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53531), we finalized 59 measures for the Hospital IQR Program measure set for the FY 2015 payment determination and subsequent years. These 59 measures are listed below.

Topic	Hospital IQR program measures previously adopted for the FY 2015 payment determination and subsequent years
Acute Myocardial Infarction (AMI) Measures	
	• AMI–2 Aspirin prescribed at discharge • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival

Topic	Hospital IQR program measures previously adopted for the FY 2015 payment determination and subsequent years
	• AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) • AMI–10 Statin Prescribed at Discharge
Heart Failure (HF) Measures	
	• HF–1 Discharge instructions • HF–2 Evaluation of left ventricular systolic function • HF–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Stroke (STK) Measure Set	
	• STK–1 VTE prophylaxis • STK–2 Antithrombotic therapy for ischemic stroke † • STK–3 Anticoagulation therapy for Afib/flutter † • STK–4 Thrombolytic therapy for acute ischemic stroke † • STK–5 Antithrombotic therapy by the end of hospital day 2 † • STK–6 Discharged on Statin † • STK–8 Stroke education † • STK–10 Assessed for rehab †
VTE Measure Set	
	• VTE–1 VTE prophylaxis † • VTE–2 ICU VTE prophylaxis † • VTE–3 VTE patients with anticoagulation overlap therapy † • VTE–4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol † • VTE–5 VTE discharge instructions † • VTE–6 Incidence of potentially preventable VTE †
Pneumonia (PN) Measures	
	• PN–3b Blood culture performed in the emergency department prior to first antibiotic received in hospital • PN–6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	
	• SCIP INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision • SCIP INF–2: Prophylactic antibiotic selection for surgical patients • SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery) • SCIP INF–4: Cardiac surgery patients with controlled 6AM postoperative serum glucose • SCIP INF–9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero • SCIP INF–10: Surgery patients with perioperative temperature management • SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period • SCIP–VTE–2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	• Acute Myocardial Infarction (AMI) 30-day mortality rate • Heart Failure (HF) 30-day mortality rate • Pneumonia (PN) 30-day mortality rate
Patients' Experience of Care Measures	
	• HCAHPS survey (expanded to include one 3-item care transition set * and two new ''About You'' items) *
Readmission Measures (Medicare Patients)	
	• Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure • Heart Failure 30-day Risk Standardized Readmission Measure • Pneumonia 30-day Risk Standardized Readmission Measure • 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty * • Hospital-Wide All-Cause Unplanned Readmission (HWR) *
AHRQ Patient Safety Indicators (PSIs) Composite Measures	
	• Complication/patient safety for selected indicators (composite)
AHRQ PSI and Nursing Sensitive Care	
	• PSI–4 Death among surgical inpatients with serious treatable complications
Structural Measures	

Topic	Hospital IQR program measures previously adopted for the FY 2015 payment determination and subsequent years
	• Participation in a Systematic Database for Cardiac Surgery • Participation in a Systematic Clinical Database Registry for Stroke Care • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care • Participation in a Systematic Clinical Database Registry for General Surgery
Healthcare-Associated Infections Measures	
	• Central Line Associated Bloodstream Infection • Surgical Site Infection —SSI following Colon Surgery —SSI following Abdominal Hysterectomy • Catheter-Associated Urinary Tract Infection • MRSA Bacteremia • *Clostridium difficile* (*C. difficile*) • Healthcare Personnel Influenza Vaccination
Surgical Complications	
	• Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty *
Emergency Department (ED)Throughput Measures	
	• ED–1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital † • ED–2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status †
Prevention: Global Immunization (IMM) Measures	
	• Immunization for Influenza • Immunization for Pneumonia
Cost Efficiency	
	• Medicare Spending per Beneficiary
Perinatal Care	
	• PC–01 Elective delivery prior to 39 completed weeks of gestation */†

* New or expanded measures/items for the FY 2015 payment determination and subsequent years.
† Proposed measure for electronic reporting via CEHRT in the Hospital IQR Program (voluntary participation in CY 2014).

b. Proposed Refinements to Existing Measures in the Hospital IQR Program

We are proposing to incorporate refinements for several measures that are currently adopted in the Hospital IQR Program. These refinements have either arisen out of the NQF endorsement maintenance process, or during our internal efforts to harmonize measurement approaches. The measure refinements include the following: (1) Incorporation of the planned readmission algorithm in 30-day readmission measures for AMI, HF, PN, THA/TKA, and Hospital-Wide Readmission to match recent NQF endorsement maintenance decisions beginning in 2013; (2) expansion of CLABSI and CAUTI measures to select non-ICU locations in IPPS hospitals beginning with infections occurring on or after January 1, 2014 (consistent with NQF expansion of the measures beyond ICUs); (3) updates to SCIP Inf 4 to match recent NQF endorsement maintenance decisions beginning with January 1, 2014 discharges; and (4) an update to the MSPB measure to include Railroad Retirement Board (RRB) beneficiaries beginning in 2014. These proposed refinements are described in greater detail below.

(1) Proposed Incorporation of Planned Readmission Algorithm for 30-Day Readmission Measures

In response to stakeholder comments, we have developed an algorithm to identify readmissions that are likely to be planned as part of ongoing medical or surgical treatment. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 2.1 which detects readmissions that are typically planned and may occur within 30 days of discharge from the hospital. For more information on the methodology used to identify planned readmissions, and the list of planned diagnoses and procedures used in the algorithm, we refer to the Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*, as well as the discussion of planned readmissions under section 3025 of the Affordable Care Act in section V.G. of the preamble of this proposed rule. We submitted this algorithm for NQF review during annual maintenance of the AMI, HF, PN, and Total Hip/Total Knee Replacement readmission measures as well as for the recently adopted Hospital Wide Readmission measure.

NQF has endorsed the use of the algorithm for these measures, and we are proposing to incorporate the Planned Readmission Algorithm into the AMI, HF, PN, and Total Hip/Knee Replacement readmission measures in addition to the Hospital-Wide Readmission Measure beginning in 2013. We invite public comment on this proposal.

(2) Proposed Expansion of Collection of CLABSI and CAUTI to Select Non-ICU Locations

We are proposing to expand the collection of the CAUTI and CLABSI measures to include several non-ICU locations beginning with infections occurring on or after January 1, 2014. Those proposed locations are medical wards, surgical wards, and medical/surgical wards. This expansion is consistent with the NQF re-endorsement update to these measures allowing application of the measures beyond ICUs. We are proposing this expansion to allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for quality improvement and public reporting efforts. We invite public comment on this proposal.

(3) Proposed Refinement of SCIP–INF–4 to Match Refinements Made During NQF Reendorsement

The quality measure SCIP Infection 4, Controlled 6AM Glucose for Cardiac Surgery Patients (NQF #300), is an example of a measure that has undergone extensive changes as a result of the NQF endorsement maintenance process. The specifications have changed so substantially that we are proposing to adopt them in this proposed rule. Specifically, the NQF Steering Committee voted to change the measure from controlled glucose at 6AM to a more comprehensive measure, controlled glucose 18–24 hours post-cardiac surgery. The revised specifications also require corrective action to be documented if a post-operative glucose is over 180mg/dl. We are proposing to adopt these revised specifications for SCIP–INF–4 beginning with January 1, 2014 discharges and invite public comment on this proposal. The revised specifications for the measure can be found at *http://www.qualityforum.org/QPS/0300*.

(4) Proposed Refinement of Medicare Spending Per Beneficiary Measure (MSPB)

(a) Inclusion of Railroad Retirement Board Beneficiaries (RRB)

We are proposing a refinement to the Medicare spending per beneficiary (MSPB) measure previously finalized for the FY 2015 and subsequent years' payment determination. We are proposing to include Railroad Retirement Board (RRB) beneficiaries in the measure for the FY 2016 and subsequent years' payment determinations. We do not consider this refinement to be a substantive change. However, we are proposing this refinement through rulemaking because we explicitly stated in previous rulemaking that these beneficiaries would be excluded from the measure (76 FR 51620). Since that time, we have learned that we have complete claims data for RRB beneficiaries, and believe that eligible MSPB episodes generated by RRB hospital discharges should be included in the MSPB measure. We finalized the details of MSPB episode construction and adjustment in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51626). The effect of including RRB beneficiaries on the MSPB ratio is minimal. For the majority of hospitals, the change in their MSPB measure rates would be small—between −0.01 and 0.01.

We welcome public comment on this proposal to refine the MSPB measure to include RRB beneficiaries.

(b) Incorporating Maryland Hospitals

We are considering how best to incorporate Maryland hospitals paid under the waiver under section 1814(b)(3) of the Act into the MSPB measure. The payments made to Maryland hospitals pose a unique challenge to the payment standardization methodology currently used for the MSPB measure. Currently, hospitalizations in Maryland hospitals that are captured in the post-discharge window of the MSPB measure are standardized by applying the hospital wage index to the labor-related share of the IPPS payment, according to the methodology found on page 10 of the ''CMS Price Standardization'' document (*http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*). This approach does not account for the absence of outlier payments on Maryland claims. In order to make a comparison of Maryland hospitals to other subsection (d) hospitals paid under the IPPS, in the event that MSPB measure rates are calculated for Maryland hospitals in the future, outliers would have to be imputed. If we were to include Maryland hospitals in the MSPB measure in the future, we would do so through future rulemaking.

We welcome public comment on the best approach to including Maryland hospitals in the MSPB measure and calculating MSPB measure rates for them.

6. Proposed Additional Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

We are proposing to add five new risk-adjusted claims-based outcome measures to the Hospital IQR Program for the FY 2016 payment determination and subsequent years: (1) 30-day risk standardized COPD Readmission; (2) 30-day risk standardized COPD Mortality; (3) 30-day risk standardized Stroke Readmission; (4) 30-day risk standardized Stroke Mortality; and (5) AMI payment per Episode of Care. In section IX.A.7. of the preamble of this proposed rule, we also are proposing that hospitals may voluntarily report certain Hospital IQR measures in an electronic format.

The proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,'' which has been made available on the NQF Web site at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. We considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital IQR Program.

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. However, the statutory requirements under section 1886(b)(3)(B)(IX)(bb) of the Act provide 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.

The proposed measures are described in greater detail below.

a. Proposed Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Measure (NQF #1891)

We are proposing to include this NQF-endorsed measure in the Hospital IQR Program beginning with the FY 2016 payment determination. The MAP supports this measure. In 2007, MedPAC published a report to Congress in which it identified the seven conditions associated with the most costly potentially preventable

readmissions; among these seven, COPD ranked fourth.[60] In 2008, 12.1 million U.S. adults were estimated to have COPD resulting in approximately 672,000 hospital discharges.[61] There is also evidence of variation in outcomes at hospitals for COPD patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized readmission rate among Medicare fee-for-service (FFS) patients aged 65 or older hospitalized for COPD in 2008 was 22.0 percent, and ranged from 18.33 percent—25.03 percent across 4,546 hospitals.[62]

The AHRQ has identified COPD as an ambulatory-care-sensitive condition (ACSC). ACSCs are conditions for which good outpatient care can potentially prevent the need for hospitalization or for which early intervention can prevent complications or more severe disease.[63] Although COPD is an ACSC, readmission rates are also influenced by inpatient care.

To better assess hospital care and care transitions for COPD patients, we developed a hospital-level readmission measure for patients hospitalized with an acute exacerbation of COPD. We are proposing this measure for use in the Hospital IQR Program as well as the Hospital Readmissions Reduction Program. We discuss the measure methodology in detail in the section of this proposed rule pertaining to the Hospital Readmissions Reduction Program. We refer readers to section IX.A.6.b. of the preamble of this proposed rule on COPD for details of the measure specifications. Details on the technical specifications of the measure can also be found on our Web site at: (*http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We invite public comment on this proposal.

b. Proposed Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Measure (NQF #1893)

(1) Background

COPD affects as many as 24 million individuals in the United States and is the nation's fourth leading cause of death. Between 1998 and 2008, the number of patients hospitalized annually for acute exacerbations of COPD (AECOPD) increased by approximately 18 percent.[64 65 66] Moreover, COPD is one of the top 20 conditions contributing to Medicare costs.[67] Finally, there is evidence of variation in outcomes at hospitals for COPD patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized mortality rate among Medicare FFS patients aged 65 or older hospitalized for COPD in 2008 was 8.5 percent, and ranged from 5.9 percent to 13.5 percent across 4,537 hospitals.[68]

We are proposing to include a hospital 30-day, all-cause risk-standardized rate of mortality following an admission for an AECOPD in the Hospital IQR Program. The measure aims to address a prevalent and costly health problem in the nation. In addition, the measure aligns with our priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and reducing short term, preventable mortality rates.

We plan to implement this measure to encourage improvement of outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized mortality rates following hospitalization for an AECOPD. Clinical trials and observational studies suggest that several aspects of care provided to patients hospitalized for AECOPD can have significant effects on mortality, thus supporting the essential construct of mortality as an appropriate outcome to measure quality.[69 70 71 72] Moreover, by proposing an outcome measure, we intend to broaden the view of quality of care that encompasses more than what can be captured by merely measuring individual processes-of-care. Through outcome measures, we can capture complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures.[73 74]

The specifics of the measure methodology are included in the measure methodology report we have posted on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Please see the report for further details on the risk-adjustment statistical model.

(2) Overview of Measure

The measure is a NQF-endorsed 30-day, all-cause risk-standardized rate of mortality after admission for an AECOPD to any non-federal acute care hospital. The MAP supports this measure for inclusion in the Hospital IQR Program.

In general, the measure uses the same approach to risk-adjustment and hierarchical logistic modeling (HLM)

[60] Committee MPA. Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.

[61] American Lung Association. Trends in COPD (Chronic Bronchitis and Emphysema): Morbidity and Mortality. 2010; Available at: *http://www.lungusa.org/finding-cures/our-research/trend-reports/copd-trend-report.pdf*.

[62] Grosso L.M., Lindenauer P., Wang C., et al. Hospital-level 30-day Readmission Following Admission for an Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Report prepared for the Centers for Medicare & Medicaid Services. 2011; Available at: *http://www.qualitynet.org/*.

[63] AHRQ Quality Indicators. Fact Sheet: Prevention Quality Indicators. 2006; Available at: *http://qualityindicators.ahrq.gov/downloads/pqi/2006-Feb-PreventionQualityIndicators.pdf*.

[64] 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*.

[65] 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*.

[66] Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project *Statistics on Hospitals Stays*. 2009; Available at: *http://hcupnet.ahrq.gov/*.

[67] Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

[68] Grosso L.M., Lindenauer P., Wang C., et al. Hospital-level 30-day Mortality Following Admission for an Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Report prepared for the Centers for Medicare & Medicaid Services. 2011; Available at: *http://www.qualitynet.org*.

[69] Global strategy for Diagnosis M, and Prevention of COPD,. 2009; Available at: *http://www.goldcopd.org/*.

[70] National Institute for Health and Clinical Excellence. Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care (Partial Update):. National Collaborating Centre for Acute and Chronic Conditions. Available at: *http://www.nice.org.uk/nicemedia/live/13029/49397/49397.pdf*.

[71] Walters JA, PG Gibson, R Wood-Baker, M Hannay, EH Walters. Systemic corticosteroids for acute exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009; CD001288(1).

[72] Lightowler JV, Wedzicha JA, Elliott MW, Ram FS. Non-invasive positive pressure ventilation to treat respiratory Failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. Bmj. 2003;326(7382).

[73] Krumholz H, Normand S–L, Spertus JA, Shahian DM, Bradley EH. Measuring Performance for Treating Heart Attacks and Heart Failure: The Case for Outcomes Measurement. Health Affairs 2007;26:75–85.

[74] Bradley EH, Herrin J, Elbel B, et al. Hospital Quality for Acute Myocardial Infarction: Correlation Among Process Measures and Relationship With Short-term Mortality. The Journal of the American Medical Association 2006;296:72–8.

methodology that is specified for our inpatient outcome measures previously adopted for the Hospital IQR Program, including AMI, HF, and PN readmission and mortality measures. For a discussion of this methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations for FFS Medicare beneficiaries hospitalized with AECOPDs.

(4) Outcome

The outcome for this measure is 30-day all-cause mortality defined as a death from any cause within 30 days of the admission date for the index hospitalization. This outcome period is consistent with other NQF-endorsed publicly reported mortality measures (AMI, HF, and PN).

The measure assesses all-cause mortality not just COPD-specific mortality for several reasons. First, limiting the measure to COPD-related mortalities may limit the focus of efforts to improve care to a narrow set of approaches (such as processes that will prevent a recurrent exacerbation) as opposed to encouraging broader initiatives aimed at improving the overall in-hospital care. Second, cause of death may be unreliably recorded and it is often not possible to exclude quality issues and accountability based on the documented cause of mortality. For example, a COPD patient who develops a hospital-acquired infection may ultimately die from sepsis. It would be inappropriate to treat this death as unrelated to the care the patient received for COPD. Finally, from a patient perspective, death is the outcome that matters, regardless of cause.

(5) Cohort

COPD is a group of lung diseases characterized by airway obstruction. Patients hospitalized for an AECOPD present with varying degrees of severity ranging from a worsening of baseline symptoms (dyspnea, cough, and/or sputum) to respiratory failure. To capture the full spectrum of severity of patients hospitalized for an AECOPD, we included patients with a principal diagnosis of COPD, as well as those with a principal diagnosis of respiratory failure who had a secondary diagnosis of an AECOPD. Requiring AECOPD as a secondary code helps to identify respiratory failure due to COPD exacerbation versus another condition (for example, heart failure). For detailed information on the cohort definition please reference the COPD mortality technical report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Inclusion and Exclusion Criteria

The measure includes hospitalizations for patients 65 years or older at the time of index admission and for whom there was a complete 12 months of FFS enrollment to allow for adequate risk-adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients having a principal diagnosis of an AECOPD during the index hospitalization who were transferred from another acute care facility are excluded because the hospital where the patient was initially admitted made critical acute care decisions (including the decision to transfer and where to transfer); (2) admissions for patients enrolled in the Medicare Hospice Program any time in the 12 months prior to the index hospitalization, including the first date of the index admission are excluded because it is likely that these patients are continuing to seek comfort care and their goal may not be survival; and (3) admissions for patients that are discharged alive and against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how at risk their patients are for death relative to patients cared for by other hospitals. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race because risk-adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk adjustment would obscure.

(8) Calculating the Risk-Standardized Mortality Ratio (RSMR)

The measure is calculated using hierarchical logistic modeling (HLM). This approach appropriately 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. The HLM is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and the number of eligible patients for the measure varies from hospital to hospital. 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 COPD hospitalization, as well as those present in the claims for care at admission. The methodology, however, specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

The RSMR is calculated as the ratio of the number of predicted deaths to the number of expected deaths and then the ratio is multiplied by the national unadjusted mortality rate. The ratio is greater than one for hospitals that have more deaths that would be expected for an average hospital with similar cases and less than one if the hospital has fewer deaths 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 RSMR is a point estimate—the best estimate of a hospital's mortality rate based on the hospital's case mix. For displaying the measure 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). For more detailed information on the calculation methodology please refer to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We invite public comment on this proposal.

c. Proposed Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure

(1) Background

Stroke is an important and common diagnosis among Medicare patients. Ischemic stroke affects hundreds of thousands of adults in the United States

each year and leaves many with new disability and at increased risk for complications, recurrent stroke and clinical deterioration.[75] Hospital readmissions after stroke may result from the progression of disease, but may also be an indicator of poor care. Approximately 10 percent of stroke survivors will have a recurrent stroke within a year and one out of four stroke patients will be readmitted to the hospital.[76 77 78] Moreover, stroke is one of the top 20 conditions contributing to Medicare costs.[79] Finally, there is evidence of variation in outcomes at hospitals for stroke patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized readmission rate among Medicare FFS patients aged 65 or older hospitalized for stroke in 2007 was 14.7 percent, and ranged from 11.6 percent to 19.4 percent across 4,242 hospitals.[80]

We are proposing to include this non-NQF-endorsed hospital 30-day, all-cause risk-standardized rate of readmission following acute ischemic stroke 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 IX.A.6. of the preamble to this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we considered other available 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 a prevalent and costly health problem in the nation. In addition, the measure aligns with our priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and reduce short term, preventable readmission rates.

We plan to implement this measure to encourage improvement of outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized readmission rates following hospitalization for acute ischemic stroke. Studies have shown stroke readmission to be related to quality of care, and that improvements in care can reduce readmission rates.[81 82 83] Moreover, by proposing an outcome measure, we intend to broaden the view of quality of care that encompasses more than what can be captured by merely measuring individual processes-of-care. Through outcome measures, we can capture complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all of which contribute to patient outcomes but are difficult to measure by individual process measures.[84 85]

The specifics of the measure methodology are included in the measure methodology report we have posted on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk-adjustment statistical model.

(2) Overview of Measure

The measure is a 30-day, all-cause risk-standardized rate of readmission following hospitalization for acute ischemic stroke to any non-federal acute care hospital. The measure includes Medicare FFS patients aged 65 or older admitted for an acute ischemic stroke and assesses if the patient was readmitted within 30 days of discharge.

In general, the measure uses the same approach to risk-adjustment and HLM methodology that is specified for our inpatient outcome measures previously adopted for the Hospital IQR Program, including AMI, HF, and PN readmission and mortality measures. For a discussion of this methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Furthermore this measure, which is calculated using CMS claims or administrative data, is validated by comparing it to a medical record model in a matched cohort of admissions for which stroke medical record data and administrative claims data are available.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations for fee-for-service Medicare beneficiaries hospitalized with acute ischemic stroke.

(4) Outcome

The outcome for this measure is 30-day all-cause readmission defined as an unplanned subsequent inpatient admission to any acute care facility from any cause within 30 days of the admission date for the index hospitalization. A number of studies have demonstrated that improvements in care at the time of patient discharge can reduce 30-day readmission rates.[86 87 88] It is a timeframe in which a readmission may reasonably be attributed to the hospital care and transitional period to a non-acute setting.

The measure assesses all-cause unplanned readmission (excluding planned readmissions) rather than only stroke-specific readmissions for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care, even though not all readmissions are preventable. Second,

[75] American Heart Association, Heart Disease and Stroke Statistics—2012 Update. American Heart Association, Circulation 2012, 125:e2–e220.

[76] Sacco RL, Hauser WA, Mohr JP, Foulkes MA. One-year outcome after cerebral infarction in whites, blacks, and Hispanics. Stroke 1991;22:305–11.

[77] Andersen HE, Schultz-Larsen K, Kreiner S, Forchhammer BH, Eriksen K, Brown A. Can readmission after stroke be prevented? Results of a randomized clinical study: a postdischarge follow-up service for stroke survivors. Stroke 2000;31:1038–45.

[78] Gooding J, Jette AM. Hospital readmissions among the elderly. Journal of the American Geriatric Society 1985;33:595–601.

[79] Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

[80] Bernheim S.M., Wang C., Wang Y., et al. Hospital 30-Day Readmission Following Acute Ischemic Stroke Hospitalization Measure: Report prepared for the Centers for Medicare & Medicaid Services. 2010; Available at: *http://www.qualitynet.org*.

[81] Jack BW, Chetty VK, Anthony D, et al. A Reengineered Hospital Discharge Program to Decrease Rehospitalization. Annals of Internal Medicine 2009;150:178–88.

[82] Naylor MD, Brooten D, Cambell R, et al. Comprehensive Discharge Planning and Home Follow-up of Hospitalized Elders: A Randomized Clinical Trial. The Journal of the American Medical Association 1999; 281:613–20.

[83] Bravata DM, Ho SY, Meehan TP, Brass LM, Concato J. Readmission and death after hospitalization for acute ischemic stroke: 5-year follow-up in the Medicare population. Stroke 2007; 38:1899–904.

[84] Krumholz H, Normand S–L, Spertus JA, Shahian DM, Bradley EH. Measuring Performance for Treating Heart Attacks and Heart Failure: The Case for Outcomes Measurement. Health Affairs 2007;26:75–85.

[85] Bradley EH, Herrin J, Elbel B, et al. Hospital Quality for Acute Myocardial Infarction: Correlation Among Process Measures and Relationship With Short-term Mortality. The Journal of the American Medical Association 2006;296:72–8.

[86] Jack BW, Chetty VK, Anthony D, et al. A Reengineered Hospital Discharge Program to Decrease Rehospitalization. Annals of Internal Medicine 2009;150:178–88.

[87] Coleman EA, Parry C, Chalmers S, Min S-j. The Care Transitions Intervention: Results of a Randomized Controlled Trial. Archives of Internal Medicine 2006;166:1822–8.

[88] Anderson C, Deepak BV, Amoateng-Adjepong Y, Zarich S. Benefits of Comprehensive Inpatient Education and Discharge Planning Combined With Outpatient Support in Elderly Patients With Congestive Heart Failure. Congestive Heart Failure 2005;November–December:315–21.

limiting the measure to stroke-related readmissions may limit the focus of efforts to improve care to a narrow set of approaches (such as processes that will prevent recurrent stroke) as opposed to encouraging broader initiatives aimed overall at improving the care within the hospital and transitions from the hospital setting. Moreover, it is often hard to exclude quality issues and accountability based on the documented cause of readmission, for instance, a patient who came back with pneumonia may have aspirated due to inadequate preventive measures and therefore we would not want to discount such a readmission.

The measure does not count readmissions that are considered planned. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 2.1 which detects readmissions that are typically planned and may occur within 30 days of discharge from the hospital. For more information on the methodology used to identify planned readmissions, and the list of planned diagnoses and procedures used in the algorithm, please refer to on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The stroke readmission measure makes one modification to the planned readmissions algorithm as it does not consider readmissions as planned for patients who are readmitted for debridement of wound; infection or burn (AHRQ's Clinical Classification Software procedure category 169). Such treatments are commonly provided for decubitus ulcers that can easily be unplanned readmissions following stroke care, because such ulcers can complicate a stroke. The algorithm includes planned readmissions for common related follow-up care for stroke patients (for example, carotid endarterectomy) as well as readmissions which are generally planned regardless of the original admission (for example, a stroke patient readmitted for cholecystectomy). Unplanned readmissions that fall within the 30-day post discharge timeframe from the index admission are not counted as outcomes for the index admission if they are preceded by a planned readmission.

(5) Cohort

The cohort of index hospital admissions included in the measure is restricted to hospitalizations for ischemic stroke. The measure is limited to ischemic stroke hospitalizations for several reasons. First, ischemic strokes are the most common type of stroke, accounting for the vast majority of stroke hospitalizations.[89] Second, the etiology and prognosis of ischemic stroke is quite different than that of hemorrhagic stroke, so a combined cohort would be more heterogeneous. This heterogeneity could make it more difficult to account for a hospital's patient mix and lead to a less fair measure. Similarly, patients with transient ischemic attacks (TIAs) are not included largely due to concerns about inconsistency in the use of administrative codes to define TIA and potential for inclusion of patients without cerebrovascular conditions. For detailed information on the cohort definition, we refer readers to the stroke readmission technical report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Inclusion and Exclusion Criteria

The measure includes hospitalizations for patients 65 years or older at the time of index admission and for whom there was a complete 12 months of FFS enrollment to allow for adequate risk-adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients who die during the initial hospitalization because they are not eligible for readmission; (2) admissions for patients having a principal diagnosis of stroke during the index hospitalization and subsequently transferred to another acute care facility are excluded because the measure's focus is on hospitals that discharge patients to a non-acute setting (for example, to home or a skilled nursing facility); (3) admissions for patients that are discharged against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (4) admissions for patients without at least 30-days post-discharge enrollment in Medicare FFS are excluded because the 30-day readmission outcome cannot be assessed in this group; and (5) additional stroke admissions for patients within 30 days of discharge from an index stroke admission will be considered readmissions and not additional index admissions.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how at risk their patients are for readmission relative to patients cared for by other hospitals. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race because risk-adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk-adjustment would obscure.

(8) Calculating the Risk Standardized Readmission Ratio (RSRR)

The measure is calculated using HLM. This approach appropriately 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. HLM is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and the number of eligible patients for the measure varies from hospital to hospital. 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 ischemic stroke hospitalization, as well as those present in the claims for care at admission. However, the methodology specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities. In addition, the measure takes into account situations where patients initially present at one ED but are then admitted to another hospital for their index stroke hospitalization. The measure includes a risk-adjustment factor to account for ED-transfer patients.

The RSRR is calculated as the ratio of the number of predicted readmissions to the number of expected readmissions and then the ratio is multiplied by the national unadjusted readmission rate. The ratio is greater than one for hospitals that have more readmission that would be expected for an average hospital with similar cases and less than one if the hospital has fewer readmissions 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 RSRR is a point estimate—the best estimate of a hospital's readmission

[89] Thom T, Haase N, Rosamond W, et al. Heart Disease and Stroke Statistics—2006 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Journal of the American Heart Association 2006:85–151.

rate based on the hospital's case mix. For displaying the measure 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). For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We are proposing to adopt this measure in the Hospital IQR Program for the FY 2016 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we considered other available measures that have been endorsed or adopted by the NQF, and were unable to identify any other NQF-endorsed measures that assess stroke readmission with a standard period of follow-up. We also are not aware of any other 30-day stroke readmission measures that have been endorsed or adopted by a consensus organization. The development of this measure went through the same rigorous development process as the other publicly reported outcomes measures and involved extensive input by stakeholders and clinical experts. It follows the same scientific approach to evaluate hospital performance as other Hospital IQR Program outcome measures. Finally, it has been validated with medical record measures and shown to produce similar hospital-level results. Accordingly, we are proposing to adopt the 30-day stroke readmission measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

We invite public comment on this proposal.

d. Proposed Hospital 30-Day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure

(1) Background

Stroke is an important and common diagnosis among Medicare patients. Stroke affects approximately 795,000 people each year in the U.S. with high rates of mortality and morbidity. Stroke is the fourth most common cause of death after heart disease, cancer, and chronic lower respiratory disease.[90] Moreover, stroke is one of the top 20 conditions contributing to Medicare costs.[91] Finally, there is evidence of variation in outcomes at hospitals for stroke patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized mortality rate among Medicare FFS patients aged 65 or older hospitalized for stroke in 2007 was 15.3 percent, and ranged from 10.7 percent to 23.5 percent across 4,288 hospitals.[92]

We are proposing to include a non-NQF endorsed hospital 30-day, all-cause risk-standardized rate of mortality following an admission for acute ischemic stroke 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 IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we considered other available 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 important to adopt this measure as it aims to address a prevalent and costly health problem in the nation. In addition, the measure aligns with our priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and reducing short term, preventable mortality rates.

We plan to implement this measure to encourage improvement of outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized mortality rates following hospitalization for acute ischemic stroke. Studies have shown stroke mortality to be related to quality of care, and that there are effective interventions that hospitals can adopt to reduce mortality rates.[93] [94] Moreover, by proposing an outcome measure, we intend to broaden the view of quality of care that encompasses more than what can be captured by merely measuring individual processes-of-care. Through outcome measures, we can capture complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all of which contribute to patient outcomes, but are difficult to measure by individual process measures.[95] [96]

The specifics of the measure methodology are included in the measure methodology report we have posted on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk-adjustment statistical model.

(2) Overview of Measure

The measure is a 30-day, all-cause risk-standardized rate of mortality after admission for acute ischemic stroke to any non-federal acute care hospital. The measure includes Medicare fee-for-service patients aged 65 or older admitted for an acute ischemic stroke and assesses if the patient died within 30 days of admission.

In general, the measure uses the same approach to risk-adjustment and HLM methodology that is specified for our inpatient outcome measures previously adopted for the Hospital IQR Program, including AMI, HF, and PN readmission and mortality measures. For a discussion of this methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Furthermore this measure, which is calculated using CMS claims or administrative data, is validated by comparing it to a medical record model in a matched cohort of admissions for which stroke medical record data and administrative claim data are available.

[90] American Heart Association, Heart Disease and Stroke Statistics—2012 Update. American Heart Association, Circulation 2012, 125:e2–e220.

[91] Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

[92] Bernheim S.M., Wang C., Wang Y., et al. Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure: Report prepared for the Centers for Medicare & Medicaid Services. 2010; Available at: *http://www.qualitynet.org*.

[93] Fonarow GC, Reeves MJ, Zhao X, et al. Age-Related Differences in Characteristics, Performance Measures, Treatment Trends, and Outcomes in Patients With Ischemic Stroke. Journal of the American Heart Association 2010;121:879–91.

[94] Bravata DM, Wells CK, Lo AC, et al. Processes of Care Associated With Acute Stroke Outcomes. Archives of Internal Medicine 2010;170:804–10.

[95] Krumholz H, Normand S-L, Spertus JA, Shahian DM, Bradley EH. Measuring Performance for Treating Heart Attacks and Heart Failure: The Case for Outcomes Measurement. Health Affairs 2007;26:75–85.

[96] Bradley EH, Herrin J, Elbel B, et al. Hospital Quality for Acute Myocardial Infarction: Correlation Among Process Measures and Relationship With Short-term Mortality. The Journal of the American Medical Association 2006;296:72–8.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations for Medicare FFS beneficiaries hospitalized with acute ischemic stroke.

(4) Outcome

The outcome for this measure is 30-day all-cause mortality defined as a death from any cause within 30 days of the admission date for the index hospitalization. Thirty days is a standard time period used in other measures of stroke mortality.[97] [98] It is a timeframe in which a death may reasonably be attributed to the hospital care and transitional period to a non-acute setting.

The measure assesses all-cause mortality as opposed to stroke-specific mortality for several reasons. First of all, limiting the measure to stroke-related mortalities may limit the focus of efforts to improve care to a narrow set of approaches (such as processes that will prevent recurrent stroke) as opposed to encouraging broader initiatives aimed at improving the overall care within the hospital. Second, cause of death may be unreliably recorded and it is often impossible to exclude quality issues and accountability based on the documented cause of mortality. For example, a stroke patient who develops a hospital-acquired infection may ultimately die from sepsis. It would be inappropriate to treat this mortality as unrelated to the care the patient received for stroke. Finally, from a patient perspective, death is the outcome that matters, regardless of cause.

(5) Cohort

The cohort of index hospital admissions included in the measure is restricted to hospitalizations for ischemic stroke. The measure is limited to ischemic stroke hospitalizations for a few reasons. First, ischemic strokes are the most common type of stroke, accounting for the vast majority of stroke hospitalizations.[99] Second, the causes and prognosis of ischemic stroke are quite different than that of hemorrhagic stroke, so a combined cohort would be more heterogeneous. This heterogeneity could make it more difficult to account for a hospital's patient mix and lead to a less fair measure. Similarly, patients with TIAs are not included largely due to concerns about inconsistency in the use of administrative codes to define TIA and potential for inclusion of patients without cerebrovascular conditions. For detailed information on the cohort definition please reference the stroke mortality technical report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Inclusion and Exclusion Criteria

The measure includes hospitalizations for patients 65 years or older at the time of index admission and for whom there was a complete 12 months of FFS enrollment to allow for adequate risk-adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients having a principal diagnosis of stroke during the index hospitalization who were transferred from another acute care facility are excluded because the hospital where the patient was initially admitted made critical acute care decisions (including the decision to transfer and where to transfer); (2) admissions for patients enrolled in the Medicare Hospice program any time in the 12 months prior to the index hospitalization, including the first date of the index admission are excluded because it is likely that these patients are continuing to seek comfort care and their goal may not be survival; and (3) admissions for patients that are discharged alive and against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how at risk their patients are for death relative to patients cared for by other hospitals. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race because risk-adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk-adjustment would obscure.

(8) Calculating the Risk Standardized Mortality Ratio (RSMR)

The measure is calculated using hierarchical logistic modeling (HLM). This approach appropriately 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. The HLM is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and the number of eligible patients for the measure varies from hospital to hospital. 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 stroke hospitalization, as well as those present in the claims for care at admission. However, the methodology specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities. In addition, the measure takes into account situations where patients initially present at one ED, are then admitted to another hospital for their index stroke hospitalization. The measure includes a risk-adjustment factor to account for ED-transfer patients.

The RSMR is calculated as the ratio of the number of predicted deaths to the number of expected deaths and then the ratio is multiplied by the national unadjusted mortality rate. The ratio is greater than one for hospitals that have more deaths that would be expected for an average hospital with similar cases and less than one if the hospital has fewer deaths than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of an ''observed'' or ''crude'' rate to an ''expected'' or risk-adjusted rate used in other similar types of statistical analyses.

The RSMR is a point estimate—the best estimate of a hospital's mortality rate based on the hospital's case mix. For displaying the measure 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). For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[97] Saposnik G, Hill MD, O'Donnell M, Fang J, Hachinski V, Kapral MK. Variables Associated With 7-Day, 30-Day, and 1-Year Fatality After Ischemic Stroke. Journal of the American Heart Association 2008;39.

[98] Counsell C, Dennis M, McDowall M, Warlow C. Predicting Outcome After Acute and Subacute Stroke: Development and Validation of New Prognostic Models Journal of the American Heart Association 2002:1041–7.

[99] American Heart Association, Heart Disease and Stroke Statistics—2012 Update. American Heart Association, Circulation 2012, 125:e2–e220.

We are proposing to adopt this measure in the Hospital IQR Program for the FY 2016 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we considered other available measures that have been endorsed or adopted by the NQF, and were unable to identify any other NQF-endorsed measures that assess stroke mortality with a standard period of follow-up. We also are not aware of any other 30-day stroke mortality measures that have been endorsed or adopted by a consensus organization. The development of this measure went through the same rigorous development process as the other publicly reported outcomes measures and involved extensive input by stakeholders and clinical experts. It follows the same scientific approach to evaluate hospital performance as other Hospital IQR outcome measures. Finally, it has been validated with medical record measures and shown to produce similar hospital-level results. Accordingly, we are proposing to adopt the 30-day stroke mortality measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

We invite public comment on this proposal.

e. Proposed Hospital Risk-Standardized Payment Associated With a 30-day Episode-of-Care for Acute Myocardial Infarction (AMI) Measure

(1) Background

Providing high-value care is an essential part of our mission to provide better health care for individuals, better health for populations, and lower costs for health care. In order to incentivize innovation that promotes high-quality care at high value it is critical to examine measures of payment and patient outcomes concurrently. There is evidence of variation in payments at hospitals for AMI patients; mean 30-day risk-standardized payment among Medicare FFS patients aged 65 or older hospitalized for AMI in 2008 was $20,207, and ranged from $15,521 to $27,317 across 1,846 hospitals.[100] 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. For this reason, the value of hospital care is more clearly assessed when pairing hospital payments with hospital quality. Therefore, we are proposing to include a non-NQF-endorsed measure: hospital risk-standardized payment associated with a 30-day episode-of-care for acute myocardial infarction (AMI) 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 IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered other available measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. The MAP supports this measure contingent on NQF-endorsement.

We believe it is important to adopt this measure as it is aligned with our 30-day AMI mortality measure and can also be paired with our 30-day AMI readmission measure. This would facilitate assessing hospital value, because including this measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* will allow stakeholders to assess information about a hospital's quality and cost of care for AMI. The measure reflects differences in the management of care for patients with AMI both during hospitalization and immediately post-discharge. AMI is a condition with substantial variation in costs of care and, therefore, is an ideal condition for assessing relative value for an episode-of-care that begins with an acute hospitalization. By focusing on one specific condition, value assessments may provide actionable feedback to hospitals and incentivize targeted improvements in care.

(2) Rationale for Examining Payments for a 30-Day Episode-of-Care

When examining variation in payments, consideration of the episode-of-care triggered by admission is meaningful for several reasons. First, hospitalizations represent a brief period of illness that requires ongoing management post-discharge and decisions made at the admitting hospital affect payments for care in the immediate post-discharge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal practice variations in the full care of the illness that can result in increased payments. Third, a 30-day preset window provides a standard observation period by which to compare all hospitals. Lastly, the AMI payment measure is intended to be paired with our 30-day AMI mortality and readmission measures and capture payments for Medicare patients across all care settings, services, and supplies, except for Medicare Part D (that is, inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, supplier Part B items, and durable medical equipment, prosthetics/orthotics, and supplies).

We have posted the measure methodology report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk adjustment statistical model as well as the model results.

(3) Overview of the Measure

The AMI payment measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for AMI for any non-federal acute care hospital. The measure includes Medicare FFS patients aged 65 or older admitted for an AMI and calculates payments for these patients over a 30-day episode-of-care beginning with the index admission. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital IQR Program, including the AMI, HF, and PN readmission and mortality measures. We refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(4) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations and payments for Medicare FFS beneficiaries hospitalized with AMI.

(5) Outcome

The primary outcome of the AMI payment measure is the hospital-level risk-standardized payment for an AMI episode-of-care. The measure captures payments for Medicare patients across all care settings, services, and supplies, except Part D. By risk-standardizing the payment measure, we are able to adjust for case-mix at any given hospital and compare a specific hospital's AMI payment to other hospitals with the same case-mix. The analytic time frame for the AMI payment measure begins

[100] Kim N., Bernheim S.M., Ott L.S., et al. Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for AMI: Report prepared for the Centers for Medicare & Medicaid Services. 2013; Available at: *http://www.qualitynet.org*.

with the index admission for AMI and ends 30 days post-admission.

In order to isolate payment variation that reflects practice patterns rather than CMS payment adjustments, the AMI payment 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 AMI.

(6) Cohort

We created the AMI payment measure cohort to be aligned with the publicly reported AMI mortality measure cohort. Consistent with these measures, the AMI payment measure includes hospitalizations with a principal hospital discharge diagnosis of AMI using the International Classification of Diseases, Ninth revision, Clinical Modification. A full list of ICD–9–CM codes included in the final cohort can be found in Appendix B of the technical report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. An index hospitalization is the initial AMI admission that triggers the 30-day episode-of-care for this payment calculation. 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).

(7) Inclusion and Exclusion Criteria

The AMI payment measure includes hospitalizations for patients 65 years or older at the time of index admission and for whom there was a complete 12 months of FFS enrollment to allow for adequate risk adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients with fewer than 30 days of post-admission enrollment in Medicare because this is necessary in order to identify the outcome (payments) in the sample over the analytic period; (2) admissions for patients having a principal diagnosis of AMI during the index hospitalization who were transferred from another acute care facility are excluded, because the hospital where the patient was initially admitted made the critical acute care decisions (including the decision to transfer and where to transfer); (3) admissions for AMI patients who were discharged on the same or next day as the index admission and did not die or get transferred are excluded, because it is unlikely these patients suffered a clinically significant AMI; (4) admissions for patients enrolled in the Medicare Hospice program any time in the 12 months prior to the index hospitalization, including the first date of the index admission are excluded, because it is likely that these patients are continuing to seek comfort care and their goal may not be survival; (5) admissions for patients who are discharged alive and against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (6) admissions for patients transferred to or from federal or Veterans Administration hospitals are excluded, because we do not have claims data for these hospitals; thus, including these patients would systematically underestimate payments; and (7) admissions without a DRG or DRG weight for the index hospitalization are excluded, because we cannot calculate a payment for these patients' index admission using the IPPS; this would underestimate payments for the entire episode-of-care.

(8) 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. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race, because risk-adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk-adjustment would obscure.

(9) Calculating the Risk Standardized Payment (RSP)

The measure is calculated using hierarchical generalized linear statistical models with a log link and an inverse Gaussian error distribution. 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. The hierarchical generalized linear model is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and sample sizes vary across hospitals. 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 AMI hospitalization, as well as those present in the claims for care at admission. This methodology specifically does not, however, account for diagnoses present in the index admission that may indicate complications 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. For displaying the measure 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). For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We are proposing to adopt the AMI payment measure in the Hospital IQR Program for the FY 2016 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been

endorsed or adopted by the NQF, and we were unable to identify any measures that assess hospital risk-standardized payment associated with a 30-day episode-of-care for acute myocardial infarction. We also are not aware of any other 30-day episode-of-care for acute myocardial infarction measures that have been endorsed or adopted by a consensus organization.

This measure is meant to be paired with our 30-day AMI mortality and/or readmission measure in order for us to gain a better understanding of the value of care for a hospital's patients and the nation as a whole. We invite public comment on this proposal.

Set out below is a table showing both the previously adopted and proposed new quality measures for the FY 2016 payment determination and subsequent years. This table does not include suspended measures and measures proposed for removal.

Topic	Previously adopted and proposed hospital IQR program measures for the FY 2016 payment determination and subsequent years
Acute Myocardial Infarction (AMI) Measures	
	• AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival • AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
Heart Failure (HF) Measures	
	• HF–2 Evaluation of left ventricular systolic function
Stroke Measure (STK) Set	
	• STK–1 VTE prophylaxis • STK–2 Antithrombotic therapy for ischemic stroke† • STK–3 Anticoagulation therapy for Afib/flutter† • STK–4 Thrombolytic therapy for acute ischemic stroke† • STK–5 Antithrombotic therapy by the end of hospital day 2† • STK–6 Discharged on Statin† • STK–8 Stroke education† • STK–10 Assessed for rehab†
VTE Measure Set	
	• VTE–1 VTE prophylaxis† • VTE–2 ICU VTE prophylaxis† • VTE–3 VTE patients with anticoagulation overlap therapy† • VTE–4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol† • VTE–5 VTE discharge instructions† • VTE–6 Incidence of potentially preventable VTE†
Pneumonia (PN) Measures	
	• PN–6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	
	• SCIP INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision • SCIP INF–2: Prophylactic antibiotic selection for surgical patients • SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery) • SCIP INF–4: Cardiac surgery patients with controlled 6AM postoperative serum glucose • SCIP INF–9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero • SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period • SCIP–VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	• Acute Myocardial Infarction (AMI) 30-day mortality rate • Heart Failure (HF) 30-day mortality rate • Pneumonia (PN) 30-day mortality rate • Stroke 30-day mortality rate*** • COPD 30-day mortality rate***
Patients' Experience of Care Measures	
	• HCAHPS survey (expanded to include one 3-item care transition set* and two new "About You" items)*
Readmission Measures (Medicare Patients)	
	• Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission Measure • Heart Failure (HF) 30-day Risk Standardized Readmission Measure • Pneumonia (PN) 30-day Risk Standardized Readmission Measure • 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty* • Hospital-Wide All-Cause Unplanned Readmission (HWR)* • Stroke 30-day Risk Standardized Readmission***

Topic	Previously adopted and proposed hospital IQR program measures for the FY 2016 payment determination and subsequent years
	• COPD 30-day Risk Standardized Readmission***
AHRQ Patient Safety Indicators (PSIs) Composite Measures	
	• Complication/patient safety for selected indicators (composite)
AHRQ PSI and Nursing Sensitive Care	
	• PSI–4 Death among surgical inpatients with serious treatable complications
Structural Measures	
	• Participation in a Systematic Database for Cardiac Surgery • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care • Participation in a Systematic Clinical Database Registry for General Surgery • Safe Surgery Checklist Use**
Healthcare-Associated Infections Measures	
	• Central Line Associated Bloodstream Infection • Surgical Site Infection —SSI following Colon Surgery —SSI following Abdominal Hysterectomy • Catheter-Associated Urinary Tract Infection • MRSA Bacteremia • *Clostridium difficile* (*C. difficile*) • Healthcare Personnel Influenza Vaccination
Surgical Complications	
	• Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty*
Emergency Department (ED) Throughput Measures	
	• ED–1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital† • ED–2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status†
Prevention: Global Immunization (IMM) Measures	
	• Immunization for Influenza
Cost Efficiency	
	• Medicare Spending per Beneficiary • AMI Payment per Episode of Care***
Perinatal Care	
	• Elective delivery prior to 39 completed weeks of gestation*/†

* New or expanded measures/items for FY 2015 payment determination and subsequent years.
** New measures for FY 2016 payment determination and subsequent years.
*** Proposed measures for FY 2016 payment determination and subsequent years.
† Proposed measure for electronic reporting via CEHRT in the Hospital IQR Program (voluntary participation in CY 2014).

7. Electronic Clinical Quality Measures

We believe that collection and reporting of data through health information technology will greatly simplify and streamline reporting for many CMS quality reporting programs. Through electronic reporting, hospitals will be able to leverage EHRs to capture, calculate, and electronically submit quality data that is currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program. As we noted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51614), we recognize the need to align and harmonize measures across hospital quality reporting programs to minimize the reporting burden imposed on hospitals. In the Medicare EHR Incentive Program Stage 2 final rule (77 FR54083 through 54087), we finalized 29 clinical quality measures from which hospitals must select a total of 16 measures covering at least three domains to report beginning in FY 2014. We anticipate that, as health information technology evolves and infrastructure is expanded, we will have the capacity to accept electronic reporting of many of the chart-abstracted measures that are currently part of the Hospital IQR Program.

Recently, we published in the **Federal Register** (78 FR 308 through 310) a Request for Information (RFI) entitled, ''Medicare Program; Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting'' to gather stakeholder feedback to determine the optimal timing and transition strategy for

adopting electronic reporting of quality measures by hospitals participating in the Hospital IQR Program. The information sent in response to the RFI was considered as the proposals set forth below were developed. We are proposing an approach that begins to align the Hospital IQR and Medicare EHR Incentive Programs by providing hospitals currently participating in the Hospital IQR Program with the option of electronically reporting a subset of measures.

We are proposing that hospitals would be able to, on a voluntary basis, electronically report 16 measures across four measure sets, (stroke [STK], venous thromboembolism [VTE], emergency department [ED] and perinatal care [PC]) in CY 2014 for the FY 2016 Hospital IQR Program payment determination. These four measure sets are also already included in the Hospital IQR Program as chart-abstracted measures. The measures in three of these four measure sets—STK, VTE, ED—(15 measures) are already included in the Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (76 FR 74489). With regard to the measure set perinatal care (PC), we stated in the 2013 IPPS/LTCH PPS final rule that we would consider electronic reporting when the e-specification of the PC–01 measure became available. The electronic specifications for these measures are included in the electronic clinical quality measure library at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. We recognize that PC–01 is a highly burdensome measure for hospitals to report via chart abstraction. Also, we do not believe that the measures, in their electronically specified form, are substantively different than they are in their chart-abstracted form, although we recognize that the EHR-based extraction methodology is different from the chart abstraction data collection methodology.

We considered proposing to require hospitals to electronically report either a greater or lesser number of Hospital IQR quality measures. Based on the RFI comments, we grew concerned that hospitals, vendors and other stakeholders might not be able to comply with a requirement to report certain quality measures electronically in CY 2014. As a result, we are proposing to make electronic reporting voluntary in CY 2014. We strongly encourage participation in voluntary electronic reporting during CY 2014 to prepare for required electronic reporting that we intend to propose for certain measures beginning in CY 2015. The proposed requirements for electronic reporting are discussed below in section IX.A.9.d.of the preamble of this proposed rule. We invite public comment on this proposal.

8. Possible New Quality Measures and Measure Topics for Future Years

We anticipate that, as EHR technology evolves, hospitals will electronically report all chart-abstracted clinical process of care and HAI measures which are currently part of the Hospital IQR Program or which have been proposed for adoption into the Program. As stated above, we intend for the future direction of electronic quality measure reporting to significantly reduce administrative burden on hospitals under the Hospital IQR Program. We will continue to work with measure stewards and developers to develop new measure concepts, and conduct pilot, reliability and validity testing. We believe that this proposal will provide hospitals and CMS with the ability to test systems in CY 2014 in order to prepare for required electronic reporting that we intend to propose for CY 2015. We believe this will simplify measure collection and submission for the Hospital IQR Program, and will reduce the burden on hospitals to report chart-abstracted measures.

We intend to propose that hospitals report additional electronic measures in an effort to reduce the burden associated with reporting chart abstracted measures and to continue to promote the adoption of CEHRT.

We are inviting public comment on our intention to add 5 new measures to be collected via EHRs in the future. The five new measures listed below were reviewed by the MAP for inclusion in the Hospital IQR Program:

- Severe Sepsis and Septic Shock Management Bundle NQF #0500 (MAP supported)
- PC–02 Cesarean Section NQF #0471 (MAP supported)
- PC–05 Exclusive Breast Milk Feeding NQF #0480 (MAP supported)
- Healthy Term Newborn NQF #0716 (MAP supported the direction of this measure)
- Hearing Screening Prior to Hospital Discharge NQF #1354 (MAP supported).

9. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (II) of the Act state that the applicable percentage increase for FY 2007 and each subsequent fiscal year shall be reduced by 2.0 percentage points (or beginning with FY 2015, 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, to the Secretary in accordance with this clause and in a form and manner, and at a time, specified by the Secretary, data required to be submitted on measures selected under this clause with respect to such a fiscal year. 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 submit quality data through the secure portion of the QualityNet (formerly known as QualityNet Exchange) Web site (*https://www.QualityNet.org*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Procedural Requirements for the FY 2016 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are now codified in regulation at 42 CFR § 412.140. Hospitals should generally refer to the regulation for participation requirements. We are, however, proposing to make three changes to the procedural requirements in this proposed rule.

We are proposing to align the last date to withdraw with the final submission deadline. The current withdrawal deadline is August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR Program payment determination will be made. We are proposing to change that deadline to May 15 prior to the start of the payment year affected in order to align with the last submission quarter deadline. For example, if a hospital wanted to withdraw from the program for the FY 2016 payment determination, the hospital would need to complete the withdrawal by May 15, 2015. We are proposing to amend the language at 42 CFR § 412.140(b) to reflect this proposal. We are proposing this change because we are striving to provide more timely feedback to hospitals regarding their annual payment update (APU) status.

We do not believe this change would add any additional burden to hospitals and it would provide CMS the ability to make earlier participation decisions. We invite public comment on this proposal.

In addition, we are proposing two technical corrections to the regulation text at 42 CFR § 412.140. The first correction is to the title of this section. The current title is ''Participation, Data Submission, and Validation Requirements under the Hospital Inpatient Quality Review (IQR) Program.'' This should state ''Participation, Data Submission, and Validation Requirements Under the Hospital Inpatient Quality Reporting (IQR) Program.'' The second technical correction is at paragraph (a)(3) which states: ''Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CNN).'' We are proposing to correct the acronym ''CNN'' to ''CCN''. The proposed language would state: ''Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CCN).''

c. Proposed Data Submission Requirements for Chart-Abstracted Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), for the FY 2015 payment determination and subsequent years, we retained the 4½ months quarterly submission deadline for chart-abstracted quality measures. We also retained the aggregate population and sampling deadline of 4 months. Hospitals would continue to be required to submit aggregate population and sample size counts to CMS on a quarterly basis for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (76 FR 51640 through 51641). We adopted the same 14-day period after the aggregate population and sample size count deadline to submit the required patient-level records. For the FY 2016 payment determination and subsequent years, hospitals must submit data for four consecutive calendar year discharge quarters. For example, for the FY 2016 payment determination, the submission quarters are as follows: 1Q CY 2014, 2Q CY 2014, 3Q CY 2014 and 4Q CY 2014. We also adopted this submission deadline for the new chart-abstracted measure for FY 2016, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation which is collected via a Web Based Tool.

For the FY 2016 payment determination and subsequent years, we are proposing to clarify the submission deadline time. Although we have historically stated that the submission deadline is 11:59 p.m., we have not clarified which time zone. For the FY 2016 payment determination and subsequent years we are proposing to clarify that submissions to QualityNet will be accepted until 11:59 p.m. Pacific time. We invite public comment on this proposal.

d. Proposed Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination

We are proposing the following approach to begin to align quality measure reporting under the Hospital IQR and Medicare EHR Incentive Programs. (We note that this proposal does not implement any statutory provisions of the HITECH Act or change any of the existing regulatory provisions of the Medicare EHR Incentive Program, which are the subject of section IX.E of the preamble of this proposed rule, separate rulemaking and public comment.) Under the Hospital IQR Program, for the FY 2016 payment determination, hospitals may choose to either (1) electronically report at least one quarter of CY 2014 quality measure data for each measure in each of four Hospital IQR measure sets (STK, VTE, ED and PC), or (2) to continue reporting all of these measures using chart-abstracted data for all four quarters of CY 2014. If a hospital chooses to electronically report the four measure sets, all of the quality measures in those four measure sets must be electronically reported for the same reporting quarter(s) although, as stated above, the hospital may choose which quarter(s) to report.

We strongly recommend hospitals electronically report the 16 measures in these four measure sets in CY 2014, to provide hospitals and CMS with the ability to test systems and adjust workflow in CY 2014 in order to prepare for required electronic reporting that we intend to propose for CY 2015 in the Hospital IQR Program. We believe this will simplify quality reporting and submission for the Hospital IQR Program, and will reduce the reporting burden on hospitals. To further incentivize hospitals to choose this option, we also intend to use the electronically reported data to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement. The hospital must also satisfy all other requirements for the Medicare EHR Incentive Program.

We are proposing different Hospital IQR Program data submission deadlines for each quarter depending on whether the hospital is submitting the data solely for the Hospital IQR Program (that is, if the hospital does not want the data to be used to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement) or whether the hospital wishes to satisfy the requirements of both programs.

If a hospital chooses to report the four measure sets electronically for the Hospital IQR Program, but does not want the data to be used to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement, the reporting periods and deadlines are as follows:

FY 2016 HOSPITAL IQR PROGRAM CHART-ABSTRACTED MEASURE REPORTING PERIODS AND DEADLINES

Discharge reporting periods	Submission deadlines
January 1, 2014–March 31, 2014	August 15, 2014.
April 1, 2014–June 30, 2014	November 15, 2014.
July 1, 2014–September 30, 2014	February 15, 2015.
October 1, 2014–December 31, 2014	May 15, 2015.

However, if the hospital does want us to use the electronically reported data to also determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement, we are proposing to modify this data submission schedule to align the reporting periods and deadlines for the Hospital IQR and Medicare EHR Incentive Programs. Specifically, we are proposing that if a hospital wants us to also use the electronically reported data to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement, the Medicare EHR Incentive Program reporting periods and deadlines could be used to satisfy the Hospital IQR Program requirements. The Medicare EHR Incentive Program clinical quality measure reporting follows the Federal fiscal year while the Hospital IQR Program follows the calendar year. The table below lists the FY 2014 Medicare EHR Incentive Program reporting periods and submission deadlines.

MEDICARE EHR INCENTIVE PROGRAM REPORTING PERIODS AND DEADLINES FY 2014 [101]

Reporting periods	Submission deadlines
For eligible hospitals in their first year of the Medicare EHR Incentive Program—Any 90 consecutive days in FY 2014 prior to July 1, 2014.	July 1, 2014.
For eligible hospitals that are beyond their first year of the Medicare EHR Incentive Program reporting electronically—Any FY 2014 quarter, or the entire FY 2014 (October 1, 2013—September 30, 2014).	November 30, 2014.

We note that the submission deadline is November 30, 2014 for hospitals that are beyond their first year of the Medicare EHR Incentive Program. Accordingly, if such a hospital chooses to electronically report 3Q CY 2014 data under the Hospital IQR Program, it would need to submit the data by November 30, 2014 (not February 15, 2015) for us to also use that data to determine whether the hospital has satisfied its Medicare EHR Incentive Program clinical quality measurement requirement. In addition, as noted above, the hospital must satisfy all other program requirements established for the Medicare EHR Incentive Program.

We also note that because of the difference in reporting deadlines, we will not be able to use 4Q 2014 electronically submitted Hospital IQR data for purposes of determining whether a hospital has satisfied its Medicare EHR Incentive Program clinical quality measurement requirement. Hospitals, however, can still report the data electronically to meet their Hospital IQR Program requirements.

We are proposing in section IX.E. of the preamble of this proposed rule to extend the beginning of the electronic submission period to January 2. If finalized, we note that hospitals in their first year of demonstrating meaningful use could also electronically submit the four measure sets (STK, VTE, ED and PC) for one quarter by July 1, 2014 to meet the clinical quality measure reporting criteria for the Medicare EHR Incentive Program as well as the Hospital IQR Program reporting requirement for those measure sets. We are also proposing that hospitals choosing to report at least one quarter of quality measure data electronically would not need to submit chart-abstracted quality measure data for the other quarters in CY 2014 for these four measure sets (STK, VTE, ED and PC).

For hospitals choosing to report electronically in the Hospital IQR Program, we are proposing that hospitals submitting these four measure sets electronically must use the Medicare EHR Incentive Program process for electronically submitting quality measure data into QualityNet (for EHR-based reporting). We are proposing Hospital IQR Program hospitals follow the submission requirements finalized in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54080). Hospitals will utilize their existing QualityNet account to submit electronic quality measure data. Specific submission procedures will be posted on the QualityNet Web site at: *https://www.qualitynet.org/*. We are proposing to align with the case threshold exemption from the Medicare EHR Incentive Program, which means that for each quality measure for which hospitals do not have a minimum number of patients that meet the patient population denominator criteria for the relevant EHR reporting period, hospitals will have the ability to declare a ''case threshold exemption'' of five or fewer discharges. Our intent is to finalize the same process in both the Medicare EHR Incentive Program and the Hospital IQR Program as further detailed below.

In preparation for this transition to electronic quality measure reporting under the Hospital IQR Program, we are proposing that if a hospital chooses to report the four measure sets (STK, VTE, ED and PC) electronically during CY 2014, the hospital's data will be extracted from the Certified Electronic Health Record Technology (CEHRT) and submitted to CMS using the Health Level Seven (HL7) Quality Reporting Document Architecture (QRDA) Category I Revision 2 standard. Certified EHR Technology is defined for the Medicare EHR Incentive Program at 42 CFR § 495.4 and 45 CFR § 170.102.

We recognize that a small percentage of Hospital IQR Program-participating hospitals are not currently participating in the Medicare EHR Incentive Program and that this proposal may not be applicable to those hospitals. These hospitals should continue to report the four measure sets using chart-abstraction. However, we believe greater adoption of CEHRT and reporting of quality measures electronically across Medicare hospital quality reporting will reduce the administrative burden on hospitals associated with the reporting of chart-abstracted quality measures. This will help hospitals to meet both Hospital IQR Program and Medicare EHR Incentive Program requirements with a streamlined data submission to CMS. We invite public comment on this proposal.

In the recent HHS ONC final rule regarding standards, implementation specifications, and certification criteria for health information technology (77 FR 54163 through 54292), HHS adopted ''2014 Edition'' EHR certification criteria that will require CEHRT to provide the capability to submit electronic clinical quality measure data in the HL7 QRDA Category I standard to support patient-level data submissions. We do not believe that our proposal to use QRDA Category I (patient-level) data under the Hospital IQR Program will create a new reporting burden for hospitals because we already require hospitals to submit ''all-payer'' patient-

[101] We refer readers to Tables 5 and 6 at 77 FR 54051.

level data under the Hospital IQR Program.

The QRDA standard specifies the framework for quality reporting, standardizes measure-defined data elements for interoperability between organizations, and is used to transmit clinical quality measure data needed to meet meaningful use (MU) requirements under the Medicare EHR Incentive Program.

We are proposing that we will not publicly report data collected from hospitals choosing to report these four measure sets electronically in CY 2014. After reviewing comments we received from our Request for Information (RFI) entitled ''Medicare Program; Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting'' (78 FR 308 through 310), it became clear that we should consider not publicly reporting clinical quality measure data submitted electronically for the four proposed measure sets due to possible abnormalities in the data and/or the submission process that may occur during the first year of electronic reporting to CMS. This proposal will provide us time to assess the data reported to determine the optimal timing and transition strategy for electronic quality measure reporting by hospitals participating in the Hospital IQR Program. However, we would like to recognize hospitals that report electronically and invite public comment on whether hospitals choosing electronic reporting of quality measures would like to be acknowledged on the *Hospital Compare* Web site as ''Pioneers'' in Medicare EHR-based reporting. However, the data results for Medicare EHR-based measures would not be publicly reported.

We are concerned that a large number of hospitals would not be able to meet the Hospital IQR Program requirements for FY 2016 if we proposed to require hospitals to electronically report the four measure sets. Accordingly, we believe this proposal—providing hospitals the opportunity for voluntary electronic submission of data for one quarter of CY 2014 discharges—represents a balanced policy that some hospitals will be able to take advantage of while ensuring that the FY 2016 Hospital IQR Program requirements are attainable for all participating hospitals. As we move further toward alignment of quality measures reporting among our reporting initiatives, we intend to propose in the future to require hospitals to report electronically specified quality measures. We invite public comment on this approach.

We are not proposing to validate any of the data that is electronically reported for the FY 2016 Hospital IQR Program. However, we share the concern among hospitals, vendors, and other stakeholders that there is a need to develop a comprehensive validation process that applies to electronically reported data. We intend to develop and propose to adopt a data validation strategy for electronically reported quality measure data in the FY 2015 IPPS/LTCH PPS proposed rule. This strategy will be informed, in part, by comments we receive in response to this proposed rule. We invite public comment regarding potential data validation methodologies.

e. Sampling and Case Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), we continued, for the FY 2015 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) regarding hospital submission of population and sampling data. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), we did not make any changes to these requirements. For the FY 2016 payment determination and subsequent years, we are not proposing to make any changes to these requirements.

We strongly recommend that hospitals review the QIO Clinical Warehouse Feedback Reports and the Hospital IQR Program Provider Participation Reports that are available after patient-level data are submitted to the QIO Clinical Warehouse. We generally update these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

f. Proposed HCAHPS Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), we adopted the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), we made one change to these requirements. Beginning with discharges occurring in third quarter CY 2011, we established that hospitals will have about 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), for the FY 2016 Hospital IQR Program payment determination, we continued these HCAHPS requirements.

For the FY 2017 payment determination and subsequent years, we are proposing to retain these requirements. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS *Quality Assurance Guidelines* and the quarterly data submission deadlines, both of which are posted at *http://www.hcahpsonline.org*. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: *http://www.hcahpsonline.org*. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site. For the FY 2017 Hospital IQR Program, the HCAHPS data would be based on discharges from January 1, 2015 through December 31, 2015.

Every hospital choosing to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS survey administration.) Hospitals are strongly encouraged to submit their entire patient discharge list, excluding patients who had requested ''no publicity'' status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We emphasize that hospitals must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient MS–DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS *Quality Assurance Guidelines.*

We note that the HCAHPS *Quality Assurance Guidelines* require that hospitals maintain complete discharge

lists that indicate which patients were eligible for the HCAHPS survey, which patients were not eligible, and which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the hospital's behalf.

Hospitals must obtain and submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the hospital is too small to obtain 300 completed surveys. We wish to emphasize that the absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. If a hospital obtains fewer than 100 completed surveys, the hospital's HCAHPS scores will be accompanied by an appropriate footnote on the *Hospital Compare* Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess hospital performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) and the HCAHPS Review and Correction Report that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO Clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

In order to ensure compliance with HCAHPS survey and administration protocols, survey vendors and hospitals that self-administer the HCAHPS Survey must: (1) Meet HCAHPS Minimum Survey Requirements and Rules of Participation presented in the current HCAHPS *Quality Assurance Guidelines;* (2) adhere to the HCAHPS survey administration protocols provided in the current HCAHPS *Quality Assurance Guidelines* and updated through HCAHPS Bulletins and announcements on the official HCAHPS On-Line Web site, *www.hcahpsonline.org*; and (3) participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS *Quality Assurance Guidelines.* All materials relevant to survey administration will be subject to review.

The systems and program review includes, but is not limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We point out that the HCAHPS *Quality Assurance Guidelines* state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS survey. If we determine that a hospital is not compliant with HCAHPS program requirements, we may determine that the hospital is not submitting HCAHPS data that meet the requirements of the Hospital IQR Program.

We strongly recommend that hospitals approved to self-administer the HCAHPS Survey attend both HCAHPS Introductory Training and HCAHPS Update Training every year. The dates of HCAHPS training session are announced on the HCAHPS On-Line Web site, *www.hcahpsonline.org*.

The HCAHPS Survey is available in official translations in several languages other than English: Spanish (mail and telephone modes); Chinese (mail mode); Russian (mail mode); and Vietnamese (mail mode). All official translations of the HCAHPS Survey instrument are available in the current HCAHPS *Quality Assurance Guidelines.* We strongly encourage hospitals with a significant patient population that speaks Spanish, Chinese, Russian or Vietnamese to offer the HCAHPS Survey in those languages. We plan to offer an official translation of the HCAHPS Survey in Portuguese (mail mode) in 2013. We encourage hospitals that serve patient populations that speak languages other than those noted to request CMS to create an official translation of the HCAHPS Survey in those languages. Only the official translations of the HCAHPS Survey instrument can be implemented.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet Hospital IQR Program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS dry-run data and submit the data to My QualityNet, the secure portion of QualityNet.

We wish to emphasize that, barring the exception that the hospital is too small to obtain 300 completed surveys in a four-quarter period, IPPS hospitals that do not meet the minimum 300 completed surveys requirement may not be in compliance with the Hospital IQR Program's requirement that hospitals submit quality data in the form, manner, and time specified by the Secretary in order to receive the full APU. If we become aware of specific cases in which a hospital has not met the finalized HCAHPS survey protocols, we may determine that the hospital has failed to meet the applicable APU requirement, and will reduce that hospital's APU accordingly.

We are proposing to codify the current guideline that approved HCAHPS survey vendors and self-administering hospitals must fully comply with all HCAHPS oversight activities, including allowing CMS and its HCAHPS Project Team to perform site visits at hospitals' and survey vendors' locations. We are proposing to codify this survey requirement at § 412.140(f)(1).

We are proposing to codify the current guideline that CMS approves survey vendor applicants to administer the HCAHPS survey for hospitals clients when applicants have met the Minimum Survey Requirements and Rules of Participation listed in the current HCAHPS *Quality Assurance Guidelines* and adhere to the survey administration protocols provided in the current HCAHPS *Quality Assurance Guidelines* and occasionally updated through HCAHPS Bulletins and announcements on the official HCAHPS On-Line Web site. We are proposing to include this survey requirement at § 412.140(f)(2).

The absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling quarter period. Hospitals and HCAHPS survey vendors should regularly 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. We invite public comment

on our proposal to continue using these HCAHPS requirements for the FY 2016 payment determination and subsequent years.

g. Proposed Data Submission Requirements for Structural Measures for the FY 2015 and FY 2016 Payment Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644), beginning with FY 2013, we finalized the period of data collection for which hospitals will submit the required structural measure information once annually for the structural measures via a Web-Based Measure Tool. We finalized our proposal for FY 2014 for submission of structural measures between April 1, 2013 and May 15, 2013 with respect to the time period of January 1, 2012 through December 31, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539), we finalized our proposal to continue this policy for the FY 2015 payment determination and subsequent years.

However, in order to provide the more timely feedback to hospitals regarding APU participation status, for the FY 2015 payment determination, we are proposing to change the date that structural measures will be submitted from April 1 2014–May 15, 2014 to January 1, 2014–February 15 2014. For the FY 2016 payment determination, we are proposing that the period of data collection for which hospitals will submit the required registry participation information for the structural measures via a Web-Based Measure Tool be between January 1, 2015 and February 15, 2015, with respect to the time period of January 1, 2014 through December 31, 2014. These proposals will allow us to provide earlier feedback to hospitals regarding APU status. We invite public comment on our proposals.

h. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51644 through 51645), we adopted the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the HAI measures to NHSN. The existing data collection and submission timeframes for the HAI measures for the FY 2015 payment determination and subsequent years align with the submission timeframes for chart-abstracted measures with the exception of Healthcare Provider Influenza Vaccination as defined below. The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*.

Hospitals will have until the Hospital IQR Program final submission deadline to submit their quarterly data for CLABSI, SSI, CAUTI, MRSA *Bacteremia* and *Clostridium difficile* to NHSN. After the final Hospital IQR Program submission deadline has occurred for each calendar quarter of CY 2013, we will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), we continued the data submission and reporting standard procedures we adopted in the FY 2012 IPPS/LTCH PPS final rule, with two exceptions discussed below, for the FY 2015 payment determination and subsequent years.

The HAI measures that will be included in the FY 2016 payment determination are included in the following chart:

Topic	FY 2016 Payment Determination: Hospital Associated Infection Measures (CDC/NHSN)
	Central Line Associated Blood Stream Infection. Surgical Site Infection. Catheter-Associated Urinary Tract Infection. MRSA *Bacteremia.* *Clostridium difficile.* Healthcare Provider Influenza Vaccination.

We realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting, for example, when a hospital has no ICUs. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), we provided an exception for the CLABSI and CAUTI measures for hospitals that do not have an ICU, reducing the burden associated with reporting to NHSN.

In addition, we recognize that some facilities may perform so few procedures requiring surveillance under the SSI measure that the data may not meaningfully assess the hospital's performance on the measure. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), we provided an exception for these hospitals from the reporting requirement in any given year if the hospital performed fewer than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year. For example, a hospital that performed only 2 colon surgeries and 4 abdominal hysterectomies in CY 2013 is not required to report the SSI measure in CY 2014. We finalized our proposal to provide hospitals with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI and SSI measures, which is available on QualityNet at: *https://www.qualitynet.org/* Hospitals-Inpatient>Healthcare Associated Infections (HAI). For the FY 2016 payment determination and subsequent years, we are not proposing to make any changes to these requirements and exceptions.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51631–51633) we finalized collection of the Healthcare Provider Influenza Vaccination measure data from October 1 through March 31st to coincide with the flu season. Because this measure is collected seasonally, we are proposing to collect this measure on May 15th of the calendar year for which the season ends. For example, for the Healthcare Provider Influenza Vaccination measure collection for vaccinations given from October 1, 2013 (or when the vaccine becomes available)—March 31, 2014, the submission deadline would be May 15, 2014. We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years we are proposing to require hospitals to report the Medicare Beneficiary ID numbers to the NHSN system for all events reported for Medicare beneficiaries. The NHSN system currently supports the voluntary submission of this information, but CMS is proposing to make it mandatory for patients with HIC numbers. We make this proposal to better support our validation efforts. CMS currently matches medical records to NHSN data as part of validation. With the information available for matching,

CMS may occasionally fail to match a reported event. By requiring that hospitals report the HIC number when it is available, we increase our confidence that records reported to NHSN will appropriately be matched with the records we sample for validation. Because we cannot anticipate in advance which records may be sampled for validation, we are proposing to require that hospitals provide this information for all reported events. We invite public comment on this proposal.

10. Proposed Modifications to the Validation Process for Chart-Abstracted Measures under the Hospital IQR Program

For the FY 2015 payment determination and subsequent years, we are proposing some modifications to the validation requirements and methods we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553). As described below, these proposals are intended to strengthen the Hospital IQR Program by validating new HAI measures while simultaneously decreasing burden relative to previous years.

The procedures to which we are proposing to modify are organized into the following sections: (a) Number and timing of quarters included in validation; (b) selection of measures and sampling of charts to be included in validation; (c) procedures for computing the validation score; (d) selection of hospitals for validation of chart-abstracted measures; and (e) procedures for submitting records for validation.

a. Proposed Timing and Number of Quarters Included in Validation

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219), the quarters included in the validation effort for each year's Hospital IQR Program payment determination are the 4th calendar quarter (October through December) of the year that occurs 2 years before the payment determination and the first 3 calendar quarters (January through September) of the following calendar year. For example, as illustrated below, for the FY 2015 payment determination, the quarters previously finalized for inclusion in validation are the fourth quarter of CY 2012 through the third quarter of CY 2013. The first figure below shows the timeline and steps associated with the Hospital IQR Program and the subsequent steps in annual validation as previously finalized and as proposed.

Section 1886(o)(1)(C)(ii)(I) of the Act precludes a hospital from participating in the Hospital VBP Program for a fiscal year if the hospital is subject to the payment reduction under the Hospital IQR Program for that fiscal year. As illustrated in the figure, the process previously finalized (75 FR 50219), yields the determination of a hospital's Hospital IQR Program APU in August of every year. However, to support the hospital's payment determination under the Hospital VBP Program in a timely manner, the IQR APU determination must be made by July 1 of each year. Therefore, we are proposing the changes discussed below.

For the FY 2015 payment determination and subsequent years, we are proposing to change this requirement to include in validation only the 4th quarter of the calendar year that occurs 2 years before the payment determination and the first 2 calendar quarters (January through June) of the following calendar year. As illustrated below, for the FY 2015 payment determination, the quarters proposed for inclusion in validation are the fourth quarter of CY 2012 through the second quarter of CY 2013; and for the FY 2016 payment determination, the quarters proposed for inclusion in validation are the fourth quarter of CY 2013 through the second quarter of CY 2014.

For the FY 2016 payment determination and subsequent years, we are also proposing to change the validation requirement to include the 3rd and 4th calendar quarters of the year that occurs 2 years before the payment determination is made and the 1st and 2nd quarters of the subsequent year for validation. As discussed above, this timeframe still allows an APU determination by July 1 each year. From an operational standpoint, gathering data for the entire year is preferable to gathering data for only three quarters. Also, we believe that all four quarters of data that are used for the Hospital IQR and VBP Programs should be checked for accuracy.

However, as described further below, we will not have built the infrastructure needed to support the proposed HAI validation process by the 3rd quarter of CY 2013. Therefore, for the FY 2016 payment determination, we are proposing to validate all measures except for HAIs starting with 3rd quarter of CY 2013, and to initiate validation of HAIs in the 4th quarter of CY 2013. We invite public comment on this proposal.

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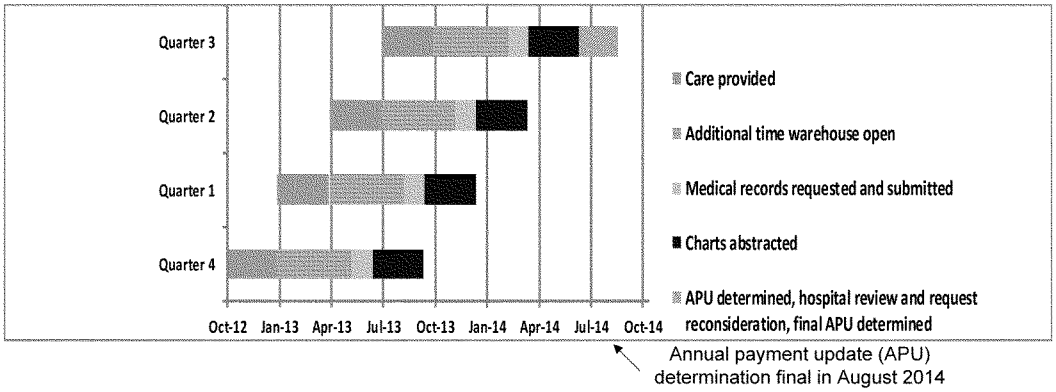
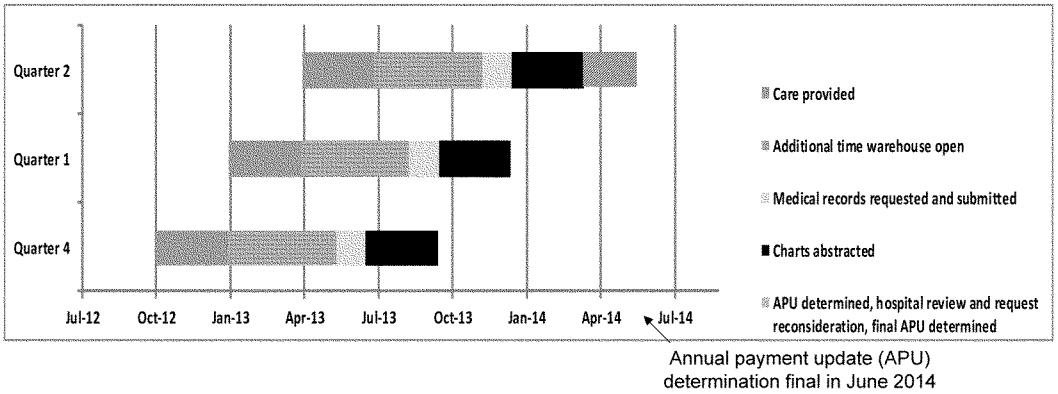
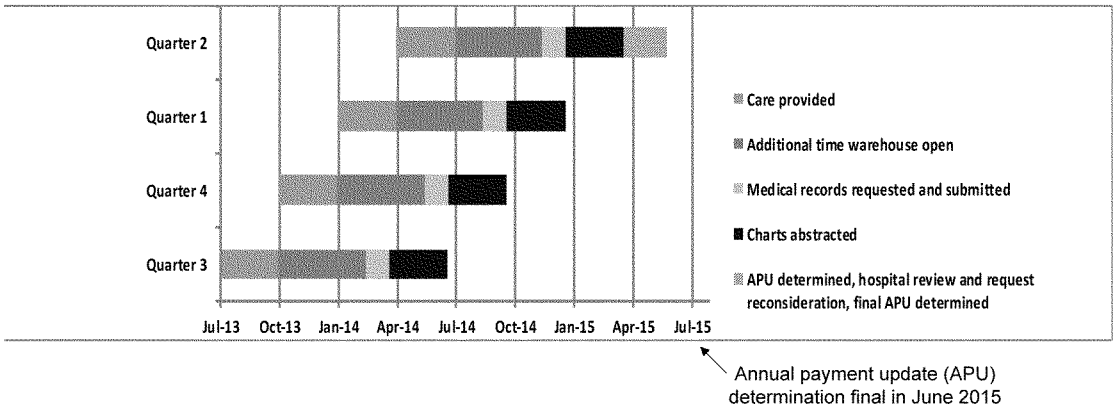
Timeline for validation of chart-abstracted measures for the FY 2015 Payment Determination, as previously finalized (75 FR 50227-50229)



Proposed timeline for validation of chart-abstracted measures for the FY 2015 Payment Determination



Proposed timeline for validation of chart-abstracted measures for the FY 2016 Payment Determination



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b. Proposed Selection of Measures and Sampling of Charts To be Included in Validation

(1) Clinical Process of Care Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53540 through 53550), for the FY 2015 payment determination and subsequent years, we finalized separate processes for selecting and scoring for validation of 21 chart-abstracted clinical process of care measures and three HAI measures. The measures finalized for validation for clinical processes of care were included in 6 measure sets: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), surgical care improvement project (SCIP), emergency department (ED) and immunization (IMM) (77 FR 53541 through 53542).

For the purposes of the FY 2016 payment determination and subsequent years, we are proposing to retain for validation 12 of the 21 chart-abstracted clinical process of care measures and to suspend validation for the remaining 9 chart-abstracted clinical process of care measures. With respect to seven of the nine measures, we are not proposing to include them in the FY 2016 measure set.

However, we are proposing to suspend validation of ED–1 and ED–2, despite their proposed inclusion in the FY 2016 measure set, because we do not operationally have the ability to validate electronically reported versions of the measures. We believe that continuing to validate the measures only when they are reported via chart-abstraction could create inequity in the validation process that favors hospitals opting to report the measures electronically. Therefore, we are proposing to delete the ED measure set from the validation process. We invite public comment on these proposals.

HOSPITAL IQR PROGRAM CHART-ABSTRACTED CLINICAL PROCESS OF CARE MEASURES PROPOSED FOR VALIDATION FOR THE FY 2016 PAYMENT DETERMINATION

Measure
AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival.
AMI–8a Timing of receipt of primary percutaneous coronary intervention.
HF–2 Evaluation of left ventricular systolic function.
PN–6 Appropriate initial antibiotic selection.
SCIP INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision.
SCIP INF–2: Prophylactic antibiotic selection for surgical patients.
SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery).
SCIP INF–4: Cardiac surgery patients with controlled 6AM postoperative serum glucose.
SCIP INF–9: Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero.
SCIP Cardiovascular–2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period.
SCIP–VTE–2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery.
IMM–2 Immunization for pneumonia.

The process for sampling of clinical process of care cases previously finalized for the FY 2015 payment determination and subsequent years in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53540 through 53541) is as follows. A sample of 15 records per quarter is to be drawn for validation of the chart-abstracted clinical process of care measures (77 FR 53540 through 53541). As finalized in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination and subsequent years, the sample is to include 3 records each sampled from among the AMI, HF, PN, and SCIP measure sets, and 3 records to validate for both the ED and IMM measures sets from among ''principal diagnoses and surgical procedures not already included in the AMI, HF, PN, and SCIP populations eligible for validation sampling in these four topic areas (76 FR 51648).'' As finalized in the FY 2012 IPPS/LTCH PPS final rule, the records sampled for AMI, HF, PN, and SCIP will also be validated for ED/IMM (76 FR 51648), but as finalized in the FY 2013 IPPS/LTCH PPS final rule these cases will not be validated from among charts sampled for HAI validation (77 FR 53540 through 53541).

We are proposing to modify this process for the FY 2016 payment determination and future years in two ways. First, we are proposing to eliminate validation of the ED measure set for the reasons described immediately above. Second, we are proposing to change the requirement to validate ED and IMM for all records included in the validation sample for AMI, HF, PN, and SCIP (77 FR 53540 through 53541). When previously finalized, this policy was intended for two purposes. When a patient chart sampled for validation for AMI, HF, PN, or SCIP also had data submitted to the warehouse for ED/IMM, we have been evaluating the accuracy of the data submitted to the warehouse for ED and IMM and including our assessment of accuracy in the validation score. In addition, when a patient chart sampled for validation for AMI, HF, PN, or SCIP did not include data submitted to the warehouse, our intention in abstracting data on ED and IMM was to assess the extent to which hospitals may have misdrawn the sample such that the ED and IMM data reported to the warehouse was inaccurate. Although it was our intention to use the data for both reasons, we have found it challenging to use the data to evaluate inaccurate sampling and have not yet done so.

Therefore, for the FY 2016 payment determination and future years, we are proposing to validate IMM for between 3 and 15 charts per hospital per quarter. These include the 3 charts sampled for IMM from among principal diagnoses and surgical procedures not already included in the AMI, HF, PN, and SCIP populations eligible for validation sampling in these four topic areas, and as many of the 12 charts sampled for AMI, HF, PN, and SCIP populations as have IMM data submitted to the warehouse. We invite public comment on this proposal.

(2) HAI Measures Included in the Current Validation Process

The three HAIs specified for chart-abstracted validation in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53542), for FY 2015 payment determination and subsequent years are CLABSI, CAUTI, and SSI for patients undergoing abdominal hysterectomies and colon procedures. HAIs are very rare events, which makes validating that they have been reported accurately more challenging than validating the clinical process of care measures. As previously finalized in the FY 2012 and FY 2013

IPPS/LTCH PPS final rules (76 FR 51645 through 51648 and 77 FR 53542 through 53548, respectively), for each HAI, we identify a set of patient episodes of care which have a much higher probability of containing a reportable HAI than others. Each quarter, we sample up to 12 of these candidates, request patient charts from hospitals to determine whether or not an HAI occurred, and score these charts by determining whether events were appropriately reported to NHSN.

In order to identify candidate cases referenced above for CLABSI and CAUTI, we also require hospitals to submit supplemental information on certain patient episodes of care quarterly. In the FY 2012 and FY 2013 IPPS/LTCH PPS final rules (76 FR 51645 through 51648 and 77 53542 through 53548, respectively), we identified the supplemental information to be provided and the types of patient episodes of care for which this information is needed. We require hospitals to submit this supplemental information in two separate ''Validation Templates'' according to formats specified on QualityNet. We require separate CLABSI and CAUTI Validation Templates because different information is required to identify candidate CLABSIs and candidate CAUTIs. For a detailed discussion of these requirements, we refer readers to our Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*.

As stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51646), for the FY 2012 payment determination and subsequent years, hospitals are required to report positive blood cultures for intensive care unit patients and are also required to ''self-identify intensive care unit patients with a CVC [central venous catheter] that are on this blood culture list.'' We are proposing for the FY 2016 payment determination and subsequent years to remove the requirement to note a CVC and replace it with a requirement to note a ''central line.'' In other words, we are proposing to require that hospitals note on the CLABSI Validation Template whether patients had a ''central line'' present at any time during their hospital stay. We are making this proposal to better align with current NHSN definitions.

The FY 2012 IPPS/LTCH PPS final rule (76 FR 51646) also specified which organisms should be reported on the CLABSI Validation Template, which are also regarded as common commensals (often referred to as skin contaminants), and where hospitals could find an updated list of these commensals. This list is frequently updated, but the link containing updates is currently out of date. When we review the CLABSI Validation Templates for the FY 2016 payment determination and subsequent years, we are proposing to apply the most up-to-date list available at the time of review. At present that list may be found at: *http://www.cdc.gov/nhsn/acute-care-hospital/clabsi/index.html*.

We also are proposing for the FY 2016 payment determination and subsequent years that hospitals must *exclude* from CAUTI Validation Templates urine cultures with more than 2 organisms, even if they have greater than or equal to 1,000 colony-forming units (CFUs)/ml. We are making this proposal because, when we finalized the requirement to include on the CAUTI Validation Templates all urine cultures with greater than or equal to 1,000 CFUs/ml (77 FR 53542 through 53545), our intention was to identify urine cultures that conform to NHSN definitions for CAUTI. Although these definitions vary, all require that there be no more than 2 organisms identified in the result (because multiple organisms often indicate contamination).[102] We invite public comment on this proposal.

We are proposing for the FY 2016 payment determination and subsequent years to notify hospitals of future changes to the definition of candidate HAI events through HAI Validation guidance documents to be posted annually on QualityNet. As illustrated by several proposals immediately above identifying places where CMS and NHSN are slightly misaligned, we believe that these very detailed specifications may more appropriately be addressed through sub-regulatory guidance than through the rulemaking process. Therefore, we are making this proposal to simplify future proposed rules regarding validation, to ensure that we are able to remain current with NHSN guidance and protocols, and to ensure that hospitals are made aware of these updates. We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years, we also are proposing to exclude from HAI validation all patient episodes of care with lengths of stay of more than 120 days. Patient episodes of care involving lengths of stay over 120 days are very rare, accounting for much less than one percent of the records submitted for Q1 2012 CLABSI validation. Because medical records for patients with very long lengths of stay may be tens of thousands of pages, the burden and costs of validation to hospitals and CMS are disproportionate to the information gained from their validation. In addition, this proposed change aligns the HAI episode of care maximum length of stay with the Hospital IQR Program's clinical process of care measures episode of care maximum length of stay of 120 days as detailed in the Specifications Manual for the National Hospital Inpatient Quality Measures (*http://www.qualitynet.org*). We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years, we also are proposing to require each hospital to submit data without modifications to the format within the Validation Template posted on QualityNet at the beginning of each validation cycle. We believe this requirement is needed based on our experience with the CLABSI Validation Template for the FY 2013 payment determination. We have observed that many hospitals enter the required data but alter the format of the downloadable Validation Template. For example, hospitals may change the length or format of a column or change its column name. Because our contractors must process hundreds of these templates in a matter of weeks, even minor alterations to formats of the data within the Template create significant operational delays. We will continue to give hospitals feedback on their Validation Templates prior to the submission deadline. To assist hospitals in meeting this formatting requirement, we will include formatting in future feedback. We invite public comment on this proposal.

(3) HAI Measures To Be Added to the Validation Process

For the FY 2016 payment determination and subsequent years, we are proposing to validate two new HAI measures: methicillin-resistant *staphylococcus aureus* (MRSA) *bacteremia* Laboratory-identified (LabID) Events and *Clostridium difficile* (CDI) LabID Events. MRSA and CDI were finalized for inclusion in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51631) starting with the FY 2015 payment determination. We are proposing to validate MRSA and CDI consistent with requirements under section 1886(b)(3)(B)(viii)(XI) of the Act which requires us to establish a process to validate measures included in the Hospital IQR Program as appropriate.

[102] ''Catheter-Associated Urinary Tract Infection (CAUTI) Event'' *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf*, last accessed February 19, 2013.

We invite public comment on this proposal.

For MRSA and CDI validation, we are proposing a process similar to that for CLABSI and CAUTI for the FY 2016 payment determination and subsequent years. Specifically, we are proposing to require sampled hospitals to provide to CMS or its contractor one list of final blood cultures positive for MRSA and a second list of all final stool specimens toxin positive for CDI. We note that although CMS only publicly reports hospital-onset infections, CMS requires hospitals to report both hospital and community-onset cases. We require hospitals to report community-onset cases because NHSN employs this information in risk-adjustment. Validation of MRSA and CDI requires confirmation that both hospital and community-onset cases are reported correctly and completely. Therefore, for the FY 2016 payment determination and subsequent years, we are proposing that both types of cases be included on the MRSA and CDI Validation Templates.

For these payment determinations, we are proposing to collect the following information on the MRSA and CDI Validation Templates needed to identify each candidate event: (1) Laboratory accession number, collection date, and location; (2) necessary information to identify the patient (that is, patient identifier, Medicare Beneficiary number also known as the health insurance claim [HIC] number, sex, and date of birth); (3) the patient's admission and discharge dates; and (4) necessary information to identify the hospital (NHSN Facility ID, Provider ID/CCN, Hospital Name and State, Contact Information for the Person Completing the Template).

Draft versions of the proposed MRSA and CDI Validation Templates will be posted on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021* during the public comment period. We are proposing this approach for MRSA and CDI validation, because we believe that this is the best way for us to systematically identify candidates that are likely to yield a high proportion of cases that should have appropriately been reported to NHSN. Consistent with the process we have been using for the CLABSI and CAUTI Validation Templates, we are proposing that quarterly submission deadlines correspond to those for population and sampling data as defined in section IX.A.9.e. of the preamble of this proposed rule. We invite public comment on this proposal.

We recognize that the proposal to add two new HAI Validation Templates has the potential to increase burden to individual hospitals selected for validation. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53551 through 53553), for the FY 2015 payment determination and subsequent years, the annual validation sample includes 400 randomly selected hospitals and up to 200 hospitals sampled based on targeting criteria. To add these new Templates without increasing burden for the FY 2016 payment determination and subsequent years, we are proposing to randomly assign half of hospitals to submit templates for CLABSI and CAUTI validation and half of hospitals to submit templates for MRSA and CDI validation. We believe this proposal will limit hospital burden to that finalized in the FY 2013 IPPS/LTCH PPS final rule, because no hospital would be required to submit more than two templates per quarter.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53547 through 53548), we established a sample size of 12 records for HAI validation per quarter for the FY 2015 payment determination and subsequent years. Each quarterly sample is to be drawn from a list of patient episodes of care for all three types of candidate HAIs (CLABSI, CAUTI, and SSI) combined in one non-stratified sampling frame. For the FY 2016 payment determination and subsequent years, we are proposing to target separate sampling strata for each type of HAI. We are making this proposal because we believe that having separate sampling targets for each infection will better accommodate the very different incidence of different types of HAI events, particularly for hospitals which are to be validated for SSI, MRSA, and CDI. This proposal also supports the objective to evaluate how well each HAI is reported to NHSN when considered across all hospitals combined.

APU Determination	HAI	Number of hospitals	Number of quarters	Number of records/quarter/hospital	Number of records per hospital
FY 2015 (previously finalized)	CLABSI, CAUTI, SSI combined	Up to 600	4	12	48
In the preamble to this proposed rule					
FY 2015	CLABSI, CAUTI, SSI combined	Up to 600	3	12	36
FY 2016	CLABSI	Up to 300	3	5	15
FY 2016	CAUTI	Up to 300	3	5	15
FY 2016	MRSA	Up to 300	3	5	15
FY 2016	CDI	Up to 300	3	5	15
FY 2016	SSI	Up to 600	3	2	6
FY 2017 and subsequent years	CLABSI	Up to 300	4	3.75	15
FY 2017 and subsequent years	CAUTI	Up to 300	4	3.75	15
FY 2017 and subsequent years	MRSA	Up to 300	4	3.75	15
FY 2017 and subsequent years	CDI	Up to 300	4	3.75	15
FY 2017 and subsequent years	SSI	Up to 600	4	1.5	6

The sample sizes for each HAI proposed for the FY 2016 payment determination are shown in the table above. For hospitals submitting CLABSI and CAUTI templates, the infection-specific sample sizes per hospital per quarter proposed are: 2 for SSI, 5 for CLABSI, and 5 for CAUTI (12 per quarter). For hospitals submitting MRSA and CDI Validation Templates, the infection-specific sample sizes per hospital per quarter proposed are: 2 for SSI, 5 for MRSA, and 5 for CDI. For each hospital, in each quarter, these cases would be drawn randomly from each individual Validation Template (or from claims for SSI) from among episodes of care containing at least one candidate event. Across all hospitals and quarters combined, we are assuming that approximately 10 percent of patients with candidate CLABSI events had a CLABSI. This will yield approximately 450 hospital discharges with actual events. Assuming a design effect resulting from clustered data collection of no more than 2, this will allow us to estimate accurate reporting (+/−5 percentage points with 90 percent confidence) of CLABSI if it occurs

approximately 75 percent of the time. We developed sample size requirements based on a 75 percent score to align with CMS requirements for a 75 percent score to pass validation as specified in 42 CFR § 412.140(d)(2), and using a two-tailed 90 percent confidence interval as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53551). Based on these statistics, we believe this is the smallest sample size needed to meet the objective of accurately evaluating how well hospitals report CLABSI data to NHSN.

Because we have less data on which to base sample size calculations for CAUTI, MRSA *bacteremia,* and CDI than we have for CLABSI, we are proposing similar sample size targets for these 4 HAIs. By proposing similar sample size requirements across these 4 HAIs for the FY 2016 payment determination and subsequent years, we assure that hospitals will be required to submit the same number of records regardless of which set of Validation Templates they are assigned to submit.

For SSI, the proposed sample size assumes that most hospitals will not have more than 2 candidate SSIs per quarter. By sampling fewer SSI cases over twice as many hospitals, we ensure that the sample size for SSI validation is also adequate. Because SSI cases may be sampled without the added submission requirement of a Validation Template, we foresee no difficulty in requiring all hospitals sampled for validation to provide information for SSI. We invite public comment on these proposals.

Within each hospital for each type of HAI event each quarter, a random sample would be drawn from among patient episodes of care with at least one candidate event identified from the Validation Template (or claims data for SSI) to meet the targeted sample size. If there are not enough cases in any stratum, we are proposing for the FY 2016 payment determination and subsequent years to reallocate those cases to any stratum or strata that have more than enough cases to meet sample size targets. We are proposing to reallocate cases because different hospitals may have different relative frequencies of each HAI. The proposed reallocation process will give CMS the flexibility to meet sample size quotas in the event that one hospital has more than enough candidate MRSA events but not enough candidate CDI events and the next hospital has more than enough candidate CDI events and not enough candidate MRSA events. We invite public comment on this proposal.

For the FY 2017 payment determination and subsequent years, we are proposing to reduce the quarterly HAI sample from 12 to 9. Please see the chart above. This is to reflect the fact that we are proposing to collect data for 4 quarters instead of for 3 quarters starting with the FY 2017 payment determination (section IX.A.10.a. of the preamble of this proposed rule). When we distribute over 4 quarters, the 15 annual patient charts each for CLABSI, CAUTI, MRSA, and CDI and 6 annual patient charts each for SSI, the process produces fractions. We are proposing to request 9 patient charts by establishing quarterly targets of 3, 3, and 1 respectively for CLABSI, CAUTI, and SSI and 3, 3, and 1 respectively for MRSA, CDI, and SSI, and then randomly allocating the remaining 2 records to meet the hospital target of 9 HAIs for the quarter. We invite public comment on these proposals.

c. Proposed Procedures for Scoring Records for Validation

We are not proposing any changes to the procedures for scoring records for validation for the clinical process of care measures for the FY 2016 payment determination or subsequent years. This process was described in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226). However, we are proposing changes to the procedures for scoring records for validation of HAI measures.

(1) Scoring of CLABSI, CAUTI, and SSI

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53550 through 53551), for the FY 2015 payment determination and subsequent years), we finalized a scoring approach considering all three HAI measures simultaneously. In general, if hospitals have matched data on all three HAIs, they would receive a score of 1, and if they have a mismatch on one or more HAIs, they would receive a score of 0. For example, if a patient had a CLABSI during an episode of care and no CAUTI or SSI and the CLABSI was properly reported, the hospital received a score of 1 for that patient. We developed this approach primarily out of an interest in maximizing the information available to us about CLABSI, CAUTI, and SSI using the same set of records reviewed for all three infections at once, and because we recognized that an individual infection event could not simultaneously be attributed to more than one cause, that is, a particular infection was either a primary CLABSI, CAUTI, or SSI, but never all three at once. In addition, the records were sampled from a single unduplicated frame. With a single sampling frame for all three events, it was not always possible to determine in advance which event to evaluate for a particular case. Moreover, it is apparent that an event that was sampled because of a MRSA *bacteremia* result does not need to be evaluated for CDI or vice-versa. For both of these reasons, we are proposing for the FY 2016 payment determination and subsequent years, to evaluate and score each case only for the infection for which it was sampled as having candidate events. For example, episodes of care for patients on the CLABSI Validation Template will be evaluated and scored only for CLABSI. We invite public comment on this proposal.

We also are proposing for the FY 2016 payment determination and subsequent years to score charts selected for SSI, CLABSI, and CAUTI in the manner that scoring was finalized for CLABSI in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647). If the Clinical Data Abstraction Center (CDAC) contractor reviews a medical record and determines that patient had no CLABSI events and the hospital reported no CLABSI to NHSN, the case will receive a score of 1. If the CDAC contractor determines that the patient had a CLABSI and this was reported to NHSN, the case will also receive a score of 1. If a mismatch occurs and the CDAC contractor determined that the patient had no CLABSI when one is reported, or that the patient had a CLABSI that was not reported, the hospital will receive a score of 0. If the CMS quarterly validation process identified that 3 out of 4 total sampled records accurately reported the presence of CLABSI or did not report a CLABSI when none was present, then the hospitals' quarterly CLABSI validation score would be ¾ or 75 percent. If two or more infections are detected for a patient episode of care, the case may receive separate scores for each event. For example, if one patient episode of care included two CLABSIs, both of which were reported correctly, and reported correctly for 2 of the remaining three records evaluated for CLABSI, then the validation score for CLABSI that quarter would be ⅘ or 80 percent.

(2) Scoring of MRSA and CDI

MRSA *bacteremia* and CDI, have very different reporting requirements from other HAIs included in the Hospital IQR Program. The major difference between the case definitions for MRSA and CDI relative to other HAIs being reported as part of IQR is that MRSA and CDI are laboratory-identified events that do not require extensive clinical judgment on the part of the reporting hospital. If the laboratory events and date of hospital admission are reported accurately, CDC makes the determination as to whether

the event was community or hospital onset.

Our proposal entails evaluating each patient episode of care on a minimum of two components, with a score of 1 for each matched component and 0 for each mismatched component. We are proposing to evaluate each laboratory identified event on the following components: (1) Whether it was reported to NHSN when it should have been reported; and (2) whether the correct dates of admission and event were reported such that NHSN correctly classified the event as hospital or community onset. Each of these components contributes to an assessment of the accuracy and completeness of the public reporting result that appears on *Hospital Compare,* and each is important.

Because each candidate event will be scored on two different components, scores will be reported in multiples of two. For example, if a sampled patient episode of care has only one candidate event, and 1 out of 2 elements matched for that event, the total score for that candidate event would be 1/2. If a particular patient episode of care contains multiple candidate events, that patient episode will be evaluated on each of these events, increasing the number of possible elements to be validated by 2, one for each candidate event evaluated. The maximum number of events that we would validate for any episode of care would be 4. Therefore, the maximum possible score for any one patient episode of care would be 8 (2 × 4). NHSN has an automated process to remove events that should not have been reported to NHSN if they occurred within 14 days of a previous laboratory-identified event for the same infection. Because NHSN excludes these events automatically, we are proposing for the FY 2016 payment determination and subsequent years that hospitals will not be credited or penalized for reporting or failing to report an automatically excluded event. We invite public comment on these proposals.

(3) Combined Scores

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53549), we finalized the process for combining the clinical process of care and HAI validation scores for the FY 2015 payment determination and subsequent years scores by weighting them proportionate to the number of measures validated in each group. We are not proposing any changes to this process. Using the finalized procedure for combining the clinical process of care and HAI validation scores, the relative weights for the FY 2016 payment determination would be 12/17 for the clinical process of care measures included in validation and 5/17 for the HAI measures included in validation.

As previously finalized in the FY 2013 IPPS/LTCH PPS payment rule for the FY 2015 payment determination and subsequent years (77 FR 53551), we use the upper bound of a two-tailed 90 percent confidence interval around the combined score to determine if a hospital passes or fails validation. If this number is greater than or equal to 75 percent, then the hospital passes validation. We are not proposing changes to this methodology. We intend to post the specific formulas used to compute the confidence interval on the QualityNet Web site at least one year prior to computation as we have done in the past (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115987129*). These formulas will continue to account appropriately for the manner in which patient charts are sampled and scored for the measures corresponding to the payment determination period.

d. Proposed Procedures To Select Hospitals for Validation

In the FY 2013 IPPS/LTCH PPS final rule, for the FY 2015 payment determination and subsequent years, we finalized an annual hospital validation sample size of 400 randomly selected hospitals and a supplemental sample of up to 200 hospitals to be selected for more targeted validation (77 FR 53552 through 53553). The supplemental sample of up to 200 hospitals will include all hospitals that fail validation in the previous year and a random sample of hospitals meeting certain targeting criteria for the FY 2015 payment determination and subsequent years. The targeting criteria were finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553) for the FY 2016 payment determination and subsequent years. A summary of these criteria is set out below.

- Any hospital with abnormal or conflicting data patterns.
- Any hospital with rapidly changing data patterns.
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.
- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated.
- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

For the FY 2016 payment determination and subsequent years, we are proposing one additional criterion for targeting as follows: Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort. We are making this proposal to increase incentives for properly reporting HAI events that should have been reported to NHSN. To ensure a fair process for validation scoring, we credit hospitals for following NHSN protocols correctly. In this regard, hospitals receive credit for not reporting to NHSN candidate HAI events that we determine were not actually events and reporting candidate HAI events to NHSN that we determine were actually HAI events. We anticipate that hospitals may receive credit for not reporting many such candidate events. We believe it is appropriate to pass hospitals for following NHSN protocols correctly by not reporting non-events. However, we recognize that the Hospital VBP Program might give hospitals an unintended incentive to underreport HAI events because the lower their HAI measure rates, the more points they will earn.

Therefore, we are proposing to use evidence of severe under-reporting (less than 50 percent) as a targeting criterion for supplemental validation. In making this proposal, we recognize that the sample size of events, which should have been reported to NHSN, may not be reliable as it is a subset of the sample of 36 candidate HAI events per hospital per year. For the 30 candidate CLABSI and CAUTI records selected each year, we expect less than half of candidate events to be actual events. We would not wish to fail hospitals based upon such a small sub-sample. Instead, in such situations we would like to gather more data, which is why we are proposing to add a targeting criterion for hospitals that appear to frequently under-report HAIs. We invite public comment on this proposal.

e. Proposed Procedures for Submitting Records for Validation

(1) Separate Submission Requirements for MRSA *Bacteremia* and CDI Validation

Under section 412.140(d)(1) of our regulations, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. Historically, we have requested the

entire medical record where the content of the medical record is defined under 42 CFR § 482.24. For validation of the MRSA *bacteremia* and CDI measures for the FY 2016 payment determination and subsequent years, we are proposing to require hospitals to submit only those two specific parts of the medical record that are needed to validate these measures. For each sampled charts, the two required parts are: (1) All final positive blood cultures for MRSA and toxin-positive specimens for CDI with specimen collection dates; and (2) all documentation of the dates on which a patient was admitted to, transferred to, or discharged from each location within the hospital during his/her stay. We are proposing to request only this information because it is all that CMS needs to complete validation for these measures. Therefore, this proposal will save CMS effort in completing validation, resulting in more timely feedback to hospitals. In addition, we believe that this more limited request may alleviate burden for many hospitals. Finally, this proposal should reduce the cost to CMS in both photocopying and shipping compared with submission of the entire patient chart. We invite public comment on this proposal.

(2) Proposed Secure Transmission of Electronic Versions of Medical Information

The current regulation at 42 CFR § 412.140(d)(1) states:

''(d) *Validation of Hospital IQR Program data.* CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals. (1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the patient charts to CMS or its contractor within 30 days of the date identified on the written request.''

We are proposing that this requirement may be met by employing either of the following options each quarter: (1) A hospital may submit paper medical records, which is the form in which CMS has historically requested them; or (2) a hospital may securely transmit electronic versions of medical information for the FY 2016 payment determination and subsequent years. The intent of this proposal is to offer an additional mode through which hospitals may meet the requirement to submit patient charts. The content of the patient charts to be submitted are defined at 42 CFR § 482.24(c). We are not proposing to change the content of these charts (except for MRSA *bacteremia* and CDI as proposed in section IX.A.10.e.(1) of the preamble of this proposed rule). We are proposing this change because hospitals are rapidly adopting EHR systems as their primary source of information about patient care. Our understanding is that as of December 2012, more than 4,000 hospitals, including 77 percent of hospitals participating in the Hospital IQR Program, had enrolled in the Medicare EHR Incentive Program.

Based on the instructions that we have historically provided with written requests for records under 42 CFR § 412.140(d)(1), hospitals have only been able to submit this information in paper format. For records stored electronically, hospitals expend additional resources printing records onto paper that may be more efficiently transmitted electronically. We pay hospitals at a rate of 12 cents per page, plus shipping (70 FR 23667). In addition, the length of paper charts has been increasing, and the paper used to submit these records has an environmental impact. As shown in the table below, the average patient chart based on the most recent available statistics from our CDAC contractor, is much larger than when CMS began validating quality reporting data.

IPPS/LTCH PPS Final or Proposed Rule FY	Approximate average page length	Citation
Final 2006	140	70 FR 47702
Final 2009	150	73 FR 49075
Final 2012	275	76 FR 51828
Proposed 2014	410	.....

In examining the most recent statistics available, which are based on records submitted for 2Q 2012, most of the increase in chart length is attributable to including HAI charts in the sample; HAI charts are on average 1,500 pages long, but other inpatient chart lengths are also larger, now averaging about 300 pages. Therefore, the proposal to allow hospitals to choose between submitting paper copy patient charts and securely transmitting electronic versions of medical information has the potential for significant reduction in administrative burden, cost, and environmental impact. Furthermore, this potential for savings grows as the measures selected for Hospital IQR Program chart validation increasingly focus on HAIs.

We are proposing for the FY 2016 payment determination and subsequent years that those hospitals wishing to securely transmit electronic versions of medical information to download or copy the digital image of the patient chart onto CD, DVD, or flash drive and ship it following instructions similar to those for shipping paper copies of patient charts. The precise guidelines to achieve this process will be posted on QualityNet and included with CMS' written requests for patient charts. This proposal requires hospitals to use this single method for secure transmission of electronic versions of medical information, because it will enable us to efficiently process records and provide timely feedback to hospitals. We recognize that there may be many other methodologies under which transmission of electronic versions of medical information might occur. After evaluating several different potential approaches, we are proposing the only one available at this time that has been successfully tested. We will continue to develop and test additional technologies for secure transmission of electronic versions of medical information. We will notify hospitals through QualityNet as we acquire any new capabilities for accepting electronic versions of medical information, and to update available methodologies through future payment rules. We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years, we also are proposing to incentivize the electronic option by offering reimbursement for the labor and supply

costs of submitting electronic versions of medical information. Because hospitals can choose between the current paper and the proposed electronic option of submitting validation records, we believe that this proposal does not increase cost or burden to hospitals. We invite public comment on this proposal.

11. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2015 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), we finalized our proposal to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. For the FY 2015 payment determination and subsequent years, the submission deadline finalized for the Data Accuracy and Completeness Acknowledgement (DACA) was aligned with the final submission quarter for each fiscal year. For example, for the FY 2015 payment determination, the submission deadline for the Data Accuracy and Completeness Acknowledgement is currently May 15, 2014, with respect to the reporting period of January 1, 2013, through December 31, 2013.

In order to provide the timely feedback to hospitals regarding the APU status, we are proposing that for the FY 2015 payment determination and subsequent years, we would collect the DACA in alignment with the 3rd quarter submission deadline. This would mean, for example, the electronic acknowledgement of data accuracy and completeness for the FY 2015 payment determination would be submitted between January 1, 2014 and February 15, 2014, with respect to the reporting period of January 1, 2013 through December 31, 2013. We invite public comment on this proposal.

12. Public Display Requirements for the FY 2016 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), we continued, for the FY 2014 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for public display requirements for the FY 2012 payment determination and subsequent years. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), we did not make any changes to these requirements. For the FY 2016 payment determination and subsequent years, we are not proposing to make any changes to these requirements. As previously stated in section IX.A.9.d. of the preamble of this proposed rule, we are proposing that we would not publicly report data collected from hospitals choosing to report the four measure sets (VTE, STK, ED and PC) electronically in CY 2014.

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*. We require that hospitals sign a Notice of Participation form when they first register to participate in the Hospital IQR Program. Once a hospital has submitted a form, the hospital is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow us to publicly report the quality measures included in the Hospital IQR Program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

13. Proposed Reconsideration and Appeal Procedures for the FY 2015 Payment Determination and Subsequent Years

The Hospital IQR Program reconsideration and appeals requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651) and are found at section 412.140(e) of our regulations. The form for reconsiderations and a detailed description of the reconsideration process are available on the QualityNet Web site at: *http://www.qualitynet.org/* >Hospitals-Inpatient>Hospital Inpatient Quality Reporting Program>APU Reconsiderations. We are proposing to interpret this requirement to allow for this form to be completed online via the secure portion of the QualityNet Web site.

In the past, it has been CMS's process to allow hospitals with a quarterly Overall Validation Result of <75 percent to request a review by or appeal mismatched data element(s) to their State Quality Improvement Organization (QIO). This process requires that the CDAC contractor copy and ship all records for any hospital that receives an overall validation score of <75 percent to the State QIO. In the past two years, none of the mismatch appeals would have resulted in a change to the final APU determination. As described at § 412.140(e) of our regulations, hospitals can also request a reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. This includes reconsideration on the basis that CMS concluded it did not meet the validation requirements. We believe this process is redundant and, for the FY 2015 payment determination and subsequent years, we are proposing to remove the quarterly appeal of mismatched data elements to the State QIO. We invite public comment on this proposal.

14. Hospital IQR Program Extraordinary Circumstances Extensions or Waivers

The Hospital IQR Program extraordinary circumstances disaster extensions or waiver requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652) and can be found at 42 CFR § 412.140(c)(2). In the FY 2012 IPPS/LTCH PPS final rule, we explained the requirements for disaster extensions or waivers. The forms and a detailed description of the extension or waiver process are available on the QualityNet Web site at: *http://www.qualitynet.org/* > Hospitals-Inpatient > Hospital Inpatient Quality Reporting Program.

We are proposing to allow for not only a CEO, but also other hospital-designated personnel contact to complete and sign waiver/extraordinary circumstances forms. This proposed change would allow hospitals to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form.

In addition, we are proposing to allow for this form to be completed online via the secure portion of the QualityNet Web site securely online via the QualityNet Web site.

We also are proposing that we may grant a waiver or extension to hospitals if we determine that a systemic problem with one of our data collection systems directly affected the ability of the hospitals to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently.

If we make the determination to grant a waiver or extension, we are proposing to communicate this decision through routine communication channels to hospitals, vendors and QIOs by means of, for example, memoranda, emails, and notices on the QualityNet Web site.

We invite public comment on these proposals.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added new subsections (a)(1)(W) and (k) to section 1866 of the Act. Section 1866(k) of the Act establishes a quality reporting program for a hospital described in section 1886(d)(1)(B)(v) of the Act (referred to as a ''PPS-Exempt Cancer Hospital'' or ''PCH''). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH shall submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such a fiscal year. Section 1866(k)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, each hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data to the Secretary on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, specified by the Secretary.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies. The NQF currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development processes. We have generally adopted NQF-endorsed measures in our reporting programs. However, section 1866(k)(3)(B) of the Act provides an exception. Specifically, it 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.

Under section 1866(k)(3)(C) of the Act, the Secretary was required to publish the measure selection for PCHs no later than October 1, 2012, with respect to FY 2014.

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making public the data submitted by PCHs under the PCHQR Program. Such procedures must ensure that a PCH has the opportunity to review the data that is to be made public with respect to the PCH prior to such data being made public. The Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished by PCHs on the CMS Web site.

2. Covered Entities

Section 1886(d)(1)(B)(v) of the Act excludes particular cancer hospitals from payment under the IPPS. This proposed rule covers only those PPS-excluded cancer hospitals meeting eligibility criteria specified in 42 CFR 412.23(f).

3. Previously Finalized Quality Measures for PCHs Beginning With the FY 2014 Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program and subsequent years. Specifically, we finalized two CDC/NHSN-based HAI quality measures (outcome measures): (1) Central Line-Associated Bloodstream Infection (CLABSI); and (2) Catheter-Associated Urinary Tract Infection (CAUTI). We also finalized three cancer-specific process of care measures: (1) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer; (2) 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; and (3) Adjuvant hormonal therapy.

The finalized measures are shown below.

PCHQR PROGRAM MEASURES FINALIZED IN THE FY 2013 IPPS/LTCH PPS FINAL RULE BEGINNING WITH THE FY 2014 PROGRAM YEAR

Safety and Healthcare-Associated Infections—HAI:
- (NQF #0139) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure
- (NQF #0138) NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure

Clinical Process/Cancer-Specific Treatments:

PCHQR PROGRAM MEASURES FINALIZED IN THE FY 2013 IPPS/LTCH PPS FINAL RULE BEGINNING WITH THE FY 2014 PROGRAM YEAR—Continued

- (NQF #0223) Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
- (NQF #0559) 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 #0220) Adjuvant Hormonal Therapy

We are not proposing to remove or replace any of the previously finalized measures from the PCHQR program for the FY 2015 program year. We discussed the collection requirements and submission timeframes for these measures in the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53564).

4. Considerations in the Selection of the Quality Measures

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless section 1866(k)(3)(B) of the Act applies. Section 1866(k)(3)(B) of the Act states that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), we indicated that we have taken a number of principles into consideration when developing measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development under the Hospital IQR Program:

- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status.
- The measure set should evolve so that it includes a focused core set of measures appropriate to cancer hospitals that reflects the level of care and the most important areas of service

furnished by those hospitals. The measures should address gaps in the quality of cancer care.

- We also consider input solicited from the public through rulemaking and public listening sessions.
- We consider suggestions and input from a PCH Technical Expert Panel (TEP), convened by a CMS measure development contractor, which rated potential PCH quality measures for importance, scientific soundness, usability, and feasibility. The TEP membership includes health-care providers specializing in the treatment of cancer, cancer researchers, consumer and patient advocates, disparities experts, and representatives from payer organizations.

Like the Hospital IQR Program, the PCHQR Program also supports the National Quality Strategy, national priorities, HHS Strategic Plans and Initiatives, and CMS Strategic Plans, as well as takes into consideration the recommendations of the MAP and strives for burden reduction whenever possible.

We invite public comment on these considerations.

5. Proposed New Quality Measures

For the PCHQR Program beginning with FY 2015, we are proposing to adopt one new measure: NHSN HAI measure of Surgical Site Infection (SSI).

For the PCHQR Program beginning with FY 2016, we are proposing to adopt 13 new measures: six measures of Surgical Care Improvement Project (SCIP), six Clinical Process/Oncology Care Measures, and one Patient Experience of Care measure (the HCAHPS Survey).

All 14 of these proposed measures are NQF-endorsed. Some address inpatient care, and others address outpatient care. All of the measures address treatment provided to cancer patients in PCH inpatient or outpatient settings. In addition, the adoption of measures that apply to more than one healthcare setting is one of our objectives in promoting quality care consistently across all health care settings. The 14 proposed measures are a subset of 19 measures that we included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act. These measures were reviewed by the MAP, a multi-stakeholder body convened by the NQF for the purpose of providing input to HHS on the selection of measures, and the MAP's conclusions can be found in the ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS.'' The MAP Report can be accessed at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*.

We considered the input and recommendations provided by the MAP in selecting the 14 measures we are proposing for the PCHQR Program. Of these 14 measures, the MAP supported the inclusion of 13 of them in the PCHQR Program, and supported the direction of the proposed HCAHPS measure, noting that additional experience with the survey is needed so that the survey questions are applicable for use in the PCH settings. Although we recognize that some stakeholders would prefer that we adopt an experience of care measure developed specifically for the cancer hospital setting, we believe that other stakeholders think HCAHPS is appropriate for the cancer hospital setting, and are aware that approximately 27 percent of PCHs are currently administering HCAHPS to their patients. For these reasons, we believe that until a new patient experience measure is developed specifically for the PCH setting, the HCAHPS will provide valuable information to the public on the patient experience of care in PCHs.

In addition, the proposed measures address the National Quality Strategy domains of Patient Safety, Clinical Effectiveness, and Patient Experience/Engagement, and further our goal of aligning measures across programs because they are already in use in either the Hospital IQR Program or the PQRS Program. We describe these proposed measures in greater detail below.

a. Proposed New Measure Beginning With FY 2015—NHSN Healthcare-Associated Infection (HAI) Measure: Surgical Site Infection (SSI) (NQF #0753)

This NQF-endorsed American College of Surgeons/CDC harmonized measure of surgical site infection (SSI) meets the measure selection requirements at section 1866(k)(3)(A) of the Act, and expands upon the existing Healthcare-Associated Infections (HAIs) measurement topic that is part of the PCHQR Program. The measure addresses HAIs, a topic area widely acknowledged by HHS, the Institute of Medicine, the National Priorities Partnership and others as a high priority requiring measurement and improvement. HAIs are among the leading causes of death in the United States. The CDC estimates that as many as 2 million infections are acquired each year in hospitals and that HAIs result in approximately 90,000 deaths per year. It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs.

HAIs are largely preventable through interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, many health care consumers and organizations have called for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and give hospitals an incentive to improve infection control efforts (75 FR 50201).

Detailed specifications for this proposed measure can be found at: *http://www.cdc.gov/nhsn/TOC_manual.html*. This measure assesses the incidence of surgical site infections following colon surgeries and abdominal hysterectomies performed by PCHs and includes laparoscopic procedures. The measure rate is calculated as the Standardized Infection Ratio for each procedure type. Adult patients 18 years and older with deep incisional and organ space infections during the 30-day postoperative period are included in the measure. This measure is risk-adjusted and reported at the facility level. It is not specific to a hospital ward or setting, rather it is applicable to all postoperative patients who fall into the numerator criteria. The denominator is calculated using logistic regression models, determining the expected number of SSI's by facility and procedure type. We invite public comment on this proposed SSI measure.

b. Proposed New Measures Beginning With the FY 2016 PQHQR Program

(1) Surgical Care Improvement Project (SCIP) Measures

Measures from the Surgical Care Improvement Project (SCIP) have been collected as part of the Hospital IQR Program for most subsection (d) hospitals paid under the IPPS and reported on the *Hospital Compare* Web site for a number of years, because they assess effective care for patients undergoing surgery. In general, these measures are also applicable to patients undergoing surgery in PCHs. We are proposing to adopt six NQF-endorsed, SCIP measures for the PCHQR Program beginning with the FY 2016 program year. All six of the measures are NQF-endorsed and therefore meet the selection requirements at section 1866(k)(3)(A) of the Act.

In addition, all six of these measures were supported by the MAP for inclusion in the PCHQR Program in its February 2013 pre-rulemaking report to HHS located at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*. Four of these measures: SCIP—Inf 1 (NQF #0527); SCIP—Inf 2 (NQF #0528), SCIP—Inf 3 (NQF #0529); and SCIP—Inf 9 (NQF #0453) assess hospital performance with regard to infection prevention practices. SCIP-Card-2 (NQF #0284) assesses the continuity of beta blocker treatment during the perioperative period for cardiac patients undergoing non-cardiac surgery. SCIP—VTE 2 (NQF #0218) assesses hospital performance regarding effective preventive care for venous thromboembolism.

These measures are described below, and detailed measure specifications for all six of these measures can be found in the Hospital IQR Program Specifications Manual located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772433589*.

We invite public comment on these six proposed SCIP measures.

(A) SCIP—Inf 1: Prophylactic Antibiotics Received Within 1 Hour Prior to Surgical Incision (NQF #0527)

This measure assesses the percent of surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision. Patients who received vancomycin or a fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within 2 hours prior to surgical incision. This measure addresses the National Quality Strategy domain of Clinical Effectiveness, and complements the proposed SSI measure.

(B) SCIP—Inf 2: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)

This measure assesses the percent of surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure). A goal of prophylaxis with antibiotics is to use an agent that is safe, cost-effective, and has a spectrum of action that covers most of the probable intraoperative contaminants for the operation. This measure addresses the National Quality Strategy domain of Clinical Effectiveness, and complements the SSI measure.

(C) SCIP—Inf 3: Prophylactic Antibiotic Discontinuation Within 24 Hours After Surgery End Time (NQF #0529)

This measure assesses the percentage of surgical patients whose prophylactic antibiotics were discontinued within 24 hours after Anesthesia End Time. A goal of prophylaxis with antibiotics is to provide benefit to the patient with as little risk as possible. It is important to maintain therapeutic serum and tissue levels throughout the operation. Intraoperative re-dosing may be needed for long operations. However, administration of antibiotics for more than 24 hours after the incision is closed offers no additional benefit to the surgical patient. Prolonged administration increases the risk of *Clostridium difficile* infection and the development of antimicrobial resistant pathogens. This measure addresses the National Quality Strategy domain of Clinical Effectiveness, and complements the proposed SSI measure.

(D) SCIP—Inf 9: Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 With Day Surgery Being Day Zero (NQF #0453)

This measure assesses the percent of surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero. The risk of catheter-associated urinary tract infection (UTI) increases with longer duration of indwelling urinary catheterization. This measure complements the CAUTI measure currently adopted for the PCHQR Program.

(E) SCIP—Card 2: Surgery Patients on Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker During the Perioperative Period (NQF #0284)

This measure assesses the percent of surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period. The perioperative period for this measure is defined as the day prior to surgery through postoperative day two, with day of surgery being day zero. The American College of Cardiology/American Heart Association promote continuation of beta-blocker therapy in the perioperative period as a class I indication, and accumulating evidence suggests that titration to maintain tight heart rate control should be the goal. We believe that this measure targets an important process of care, beta blocker administration for non-cardiac surgery patients. Concerns regarding the discontinuation of beta-blocker therapy in the perioperative period have existed for several decades. This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(F) SCIP—VTE 2: Surgical Patients Who Received Appropriate VTE Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery End Time (NQF #0218)

This measure assesses the percent of surgery patients who received appropriate VTE prophylaxis within 24 hours prior to Anesthesia Start Time to 24 hours after Anesthesia End Time. The frequency of VTE, which includes deep vein thrombosis and pulmonary embolism, is related to the type and duration of surgery, patient risk factors, duration and extent of postoperative immobilization, and use or nonuse of prophylaxis. Despite the evidence that VTE is one of the most common postoperative complications and prophylaxis is the most effective strategy to reduce morbidity and mortality, it is often underused. We believe that this measure will encourage practices to reduce the risk of post-operative complications associated with VTE. This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(2) Clinical Process/Oncology Care Measures

We are proposing to add to the PCHQR Program, beginning with FY 2016, six measures specific to assessing the quality of medical treatment and staging of cancer by PPS-exempt cancer hospitals. All six measures are specified and endorsed for outpatient settings to evaluate the performance of a cancer treatment team which is an integral part of a cancer center. In addition, all six of these measures are NQF-endorsed and address the quality of outpatient cancer treatment provided at PCHs; therefore, they meet the measure selection requirement at section 1866(k)(3)(A) of the Act.

All six measures also are recommended as priorities for program alignment in the PCHQR Program by the MAP in a June 2012 Final Report entitled ''Performance Measurement Coordination Strategy for PPS-Exempt Cancer Hospitals.'' In addition, all six of the measures are supported for inclusion in the PCHQR Program by the MAP in its 2013 Pre-Rulemaking Final Report issued in February 2013. Both of these MAP reports can be located at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

Detailed specifications of these six proposed measures can be found in Appendix A of the December 2012 NQF

Cancer endorsement maintenance project report at: *http://www.qualityforum.org/Publications/2012/12/Cancer_Endorsement_Maintenance_2011.aspx*. We invite public comment on these six proposed clinical process/oncology care measures.

(A) Clinical Process/Oncology Care—Multiple Myeloma-Treatment With Bisphosphonates (NQF #0380)

This measure assesses the percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, for which intravenous bisphosphonate therapy was prescribed or received within the 12-month reporting period. This measure is intended to promote the appropriate use of bisphosphonates to reduce morbidity and mortality in multiple-myeloma patients. Bisphosphonates specifically decrease osteoclast activity, thereby reducing bone pain and fractures in patients with multiple myeloma.[103] This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(B) Clinical Process/Oncology Care—Radiation Dose Limits to Normal Tissues (NQF #0382)

This measure assesses the percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in the medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues. This measure is intended to assess the appropriate use of 3D conformal radiation therapy in the treatment of pancreatic and lung cancers. Treatment is important due to the high rate of morbidity and mortality associated with these cancers. For example, among cancers in US adults, lung cancers are the leading cause of deaths in both men and women. It is estimated from 2006–2008 rates that 6.94 percent of U.S. men and women born today will be diagnosed with cancer of the lung and bronchus at some time during their lifetime.[104]

Regarding pancreatic cancer, there has been an increased frequency of this cancer since 1998 of 0.8 percent in men and 1.0 percent in women.[105] Based on rates from 2006 through 2008, 1.45 percent of men and women born today will be diagnosed with cancer of the pancreas at some time during their lifetime. A major goal of radiation therapy is the delivery of the desired dose distribution of radiation to target tissue while limiting the radiation dose to the surrounding normal tissues to an acceptable level.

Patients treated with 3D conformal radiation therapy are often subjected to radiation dose levels that exceed normal tissue tolerance. Precise specification of maximum doses to be received by normal tissues during radiation treatment planning is considered a best practice to avoid delivering unnecessary radiation to patients.

(C) Clinical Process/Oncology Care—Plan of Care for Pain (NQF #0383)

This measure assesses the percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy, who report having pain, with a documented plan of care to address that pain. Pain is one of the most common symptoms associated with cancer, occurring in approximately one quarter of patients with newly diagnosed malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease. Proper pain management is critical to achieving pain control. ''Unrelieved pain denies [patients] comfort and greatly affects their activities, motivation, interactions with family and friends, and overall quality of life.'' [106] This measure aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment based on clinical circumstances and patient wishes.[107] This measure addresses the National Quality Strategy domain of Patient and Family Engagement. This measure is intended to be paired with NQF #0384 below.

(D) Clinical Process/Oncology Care—Pain Intensity Quantified (NQF #0384)

This measure assesses the percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified. As described above for Oncology: Plan of Care for Pain (NQF #0383), pain is the most common symptom in cancer patients and this measure is used in conjunction with NQF #0384 to encourage consistent assessment of pain intensity to better guide the care of pain.[108] This measure addresses the National Quality Strategy domain of Patient and Family Engagement. Higher rates are indicative of better performance. This measure is intended to be paired with NQF #0383 above.

(E) Clinical Process/Oncology Care—Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients (NQF #0389)

This measure assesses the percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, or external beam radiotherapy to the prostate, or radical prostatectomy, or cryotherapy, who did not have a bone scan performed at any time since diagnosis of prostate cancer.

Prostate cancer is the most commonly diagnosed cancer and the second leading cause of cancer death in men over the age of 40 years in the United States. Current guidelines and best practices do not recommend bone scans for patients in the low risk stratum for prostate cancer bony involvement. This goal of this measure is to reduce the use of bone scans that are clinically unnecessary and reduce economic burden to the patient and payer.[109] This measure addresses the National Quality Strategy domain of Clinical Efficiency.

(F) Clinical Process/Oncology Care—Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients (NQF #0390)

This measure assesses the percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence receiving external beam

[103] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

[104] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

[105] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

[106] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

[107] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

[108] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

[109] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

radiotherapy to the prostate, who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist). Prostate cancer is the most commonly diagnosed cancer and the second leading cause of cancer death in men over the age of 40 years in the United States. If patients are receiving external beam radiotherapy as primary therapy, those patients that are designated as high risk may be prescribed hormonal therapy. Adjuvant hormonal therapy in these patients has been shown to increase the effectiveness of the radiotherapy and may also prolong survival. Further, the American Urological Association and the National Comprehensive Cancer Network guidelines recommend adjuvant hormonal therapy with radiotherapy for high risk prostate cancer patients for prolonged survival. This measure attempts to encourage compliance with this guideline for this specific patient population.[110] This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(3) Patient Experience of Care Survey: HCAHPS

To advance patient safety and quality improvement in cancer hospital settings, we are proposing that for the FY 2016 PCHQR Program and subsequent years PCHs submit data on the HCAHPS Survey of patient experience-of-care. We partnered with AHRQ to develop HCAHPS. The HCAHPS Survey is the first national, standardized, publicly reported survey of patients' experience of hospital care. HCAHPS, also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.

The HCAHPS Survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask ''how often'' or whether patients experienced a critical aspect of hospital care. The survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports (77 FR 53513 through 53515).

Ten HCAHPS measures (six summary measures, two individual items and two global items) are currently publicly reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) for each hospital participating in the Hospital IQR Program. One new composite item, ''Transition to post-hospital care,'' will be added to the *Hospital Compare* Web site for the Hospital IQR Program once participating hospitals have submitted four calendar quarters of data on the three Care Transition Measure items that were added to the HCAHPS Survey beginning with January 2013 discharges (77 FR 53513 through 53515).

Each of the six currently reported summary measures, or composites, is constructed from two or three survey questions. The six composites summarize how well doctors communicate with patients, how well nurses communicate with patients, how responsive hospital staff are to patients' needs, how well hospital staff helps patients manage pain, how well the staff communicates with patients about medicines, and whether key information is provided at discharge. The two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends.

The HCAHPS Survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. Patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries. PCHs may use an approved survey vendor, or collect their own HCAHPS data (if approved by CMS to do so). To accommodate hospitals, HCAHPS can be implemented using one of four different survey modes: mail, telephone, mail with telephone follow-up, or active interactive voice recognition (IVR). Regardless of the mode used, the PCH would be required to make multiple attempts to contact patients.

PCHs may use the HCAHPS Survey alone, or include additional questions after the 21 core items discussed above. PCHs must survey patients throughout each month of the year, and PCHs participating in the PCHQR Program must target at least 300 completed surveys over four calendar quarters in order to attain the reliability criterion CMS has set for publicly reported HCAHPS scores. The HCAHPS Survey is available in official translations in several languages other than English: Spanish (mail and telephone modes); Chinese (mail mode); Russian (mail mode); and Vietnamese (mail mode). All official translations of the HCAHPS Survey instrument are available in the current HCAHPS *Quality Assurance Guidelines*. The survey itself and the protocols for sampling, data collection, coding and file submission can be found in the current HCAHPS *Quality Assurance Guidelines* manual, available on the HCAHPS On-Line Web site located at: *http://www.hcahpsonline.org*.

We partnered with AHRQ to develop and test the HCAHPS Survey. AHRQ carried out a rigorous and multi-faceted scientific process, including a public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-State pilot test; extensive psychometric analyses; consumer testing; and numerous small-scale field tests. In addition, we provided three separate opportunities for the public to comment on HCAHPS, and responded to over 1,000 comments.

In May 2005, the HCAHPS Survey was NQF-endorsed and in December 2005 OMB gave its final approval for the national implementation of HCAHPS for public reporting purposes. We implemented the HCAHPS Survey for the Hospital IQR Program in October 2006 and the first public reporting of HCAHPS results under that program occurred in March 2008. The survey, its methodology and the results it produces are available on *Hospital Compare*.

Currently, nearly 3,900 hospitals that participate in the Hospital IQR Program publicly report their HCAHPS scores on *Hospital Compare,* and about 27 percent of PCHs voluntarily administer the HCAHPs Survey. We strongly encourage those PCHs that are currently submitting the HCAHPS measure to continue their current data submission.

In summary, we invite public comment on our proposals to adopt one new measure (SSI measure) beginning with the FY 2015 PCHQR Program and 13 new measures (six SCIP measures, six Clinical Process/Oncology Care measures, and one HCAHPS measure) beginning with the FY 2016 PCHQR Program. We refer readers to section IX.B.9. of the preamble of this proposed rule for more detailed information about the form, manner, and timing of data collection for these proposed measures. The tables below list the proposed new measures for the PCHQR Program beginning with the FY 2015 and FY 2016 respectively.

[110] NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus—Phase 1. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.*

Topic	Proposed New Measure for the PCHQR Program Beginning with the FY 2015 Program Year
Safety and Healthcare-Associated Infection—HAI	
	• (NQF #0753) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure

Topic	Proposed New Measures for the PCHQR Program Beginning with the FY 2016 Program Year
SCIP	
	• (NQF #0218) Surgery Patients who Received Appropriate VTE Prophylaxis within 24 Hrs Prior to Surgery to 24 Hrs After Surgery End Time • (NQF #0453) Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 with Day of Surgery Being Day Zero • (NQF #0527) Prophylactic Antibiotic Received Within 1 Hr Prior to Surgical Incision • (NQF #0528) Prophylactic Antibiotic Selection for Surgical Patients • (NQF #0529) Prophylactic Antibiotic Discontinued Within 24 Hrs After Surgery End Time • (NQF #0284) Surgery Patients on Beta Blocker Therapy Prior to Admission who Received a Beta Blocker During the Perioperative Period
Clinical Process/Oncology Care Measures	
	• (NQF #0380) Multiple Myeloma-Treatment with Bisphosphonates • (NQF #0382) Oncology-Radiation Dose Limits to Normal Tissues • (NQF #0383) Oncology: Plan of Care for Pain • (NQF #0384) Oncology: Pain Intensity Quantified • (NQF #0390) Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients • (NQF #0389) Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients
Patient Engagement/Experience of Care	
	• (NQF #0166) HCAHPS

6. Possible New Quality Measure Topics for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the PPS-exempt cancer hospital setting. Therefore, through future rulemaking, we intend to propose to adopt new or updated measures, such as measures that assess the safety and efficiency of diagnosis and treatment of cancer, measures that take into account novel diagnostic and treatment modalities, measures that assess symptoms and functional status, measures of appropriate disease management and care coordination, and measures of admissions for complications of cancer and treatment for cancer, that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain cancer services through the widespread dissemination and use of performance information.

We welcome public comment and suggestions for the following measure domains: clinical quality of care, care coordination, patient safety, patient and caregiver experience of care, population/community health, and efficiency. These domains align with those of the National Quality Strategy, and we believe that selecting measures to address these domains will promote better cancer care while bringing the PCHQR Program in line with other established quality reporting and pay for performance programs such as the Hospital IQR Program, the Hospital VBP Program, and the Hospital OQR Program, and others within our purview.

7. Maintenance of Technical Specifications for Quality Measures

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. 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 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562), we adopted a policy to use a subregulatory process to make nonsubstantive updates to NQF-endorsed measures used for the PCHQR Program. We also said that we expected to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis, and provided examples of the types of changes that would fall into each category. We further said that the policies regarding what is considered substantive versus nonsubstantive changes would apply to all PCHQR Program measures.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS Quality Assurance Guidelines manual, which is available at HCAHPS On-Line Web site, *http://www.hcahpsonline.org*. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems. As stated in our previous rulemaking (77 FR 53562), the specifications for the other measures are posted on the Specification Manual on the QualityNet Web site at *www.qualitynet.org*.

The Specifications Manual contains links to measure specifications, data abstraction information, data submission information, and other information necessary for PCHs to participate in the PCHQR Program. We maintain the technical specifications for the quality measures by updating this Manual periodically as we continue to expand and update our PCHQR Program. These updates include detailed instructions for PCHs to use when collecting and submitting data on the required measures and are accompanied by notifications to PCHQR Program-participating users, providing sufficient time between the change and effective dates in order to allow users to

incorporate changes and updates to the measure specifications into data collection systems. We also revise the Specifications Manual and provide links to reflect measure changes which are also posted on the QualityNet Web site at: *https://www.QualityNet.org*.

8. Public Display Requirements Beginning with FY 2015 Program Year

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 shall ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospital on the CMS Web site. In order to meet these requirements, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562 through 56563), we finalized our policy to publicly display the submitted 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.

This year we have more information on the state of our systems' capability and readiness, therefore, we are proposing to publicly display in 2014 the data for the measures listed below:

- Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (NQF #0223); and
- 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).

However, at this time, we are proposing to defer the public reporting of the remaining three finalized measures for FY 2014 PCHQR Program. We are in the process of testing and assessing data quality, including the reliability and validity of the measure rates, and do not believe that the data will be ready for public posting until sometime in the future. We will provide more information in future rulemaking.

We invite public comment on these proposals.

9. Form, Manner, and Timing of Data Submission Beginning with the FY 2015 Program Year

a. Background

Section 1866(k)(2) of the Act requires that, beginning with 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.

The complete data submission requirements and submission deadlines for FY 2014 have been posted on the QualityNet Web site at: *https://www.QualityNet.org*. We also refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 535567) for more information.

b. Proposed Waivers from Program Requirements

In our experience with other quality reporting and/or performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to unduly increase their burden during these times. Therefore, we are proposing that, beginning with FY 2014, PCHs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. When waivers are granted, we will notify the respective PCH.

Under the proposed process, in the event of extraordinary circumstances not within the control of the PCH, such as a natural disaster, the PCH may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such facilities would submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- The PCH's CCN;
- The PCH's name;
- Contact information for the PCH's CEO and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);
- The PCH's reason for requesting an extension or waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the PCH will again be able to submit PCHQR Program data, and a justification for the proposed date.

We are proposing that the request form must be signed by the PCH's CEO or designee, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the request form, we would: (1) Provide a written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated PCH personnel, notifying them that the PCH's request has been received; and (2) provide a formal response to the CEO and any additional designated PCH personnel, using the contact information provided in the request, notifying them of our decision.

This proposal does not preclude us from granting waivers or extensions to PCHs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect a PCH's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver or extension to PCHs in a region or locale, we are proposing to communicate this decision through routine communication channels to PCHs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

We invite public comment on this proposal.

c. Proposed Reporting Periods and Submission Timelines for the Proposed SSI Measure

We are proposing that PCHs report the proposed SSI measure beginning with January 1, 2014 events. We believe that this date will provide enough advance notice for PCHs to prepare to report the measure, and we base this belief on our experience gained from collecting the SSI measure for the Hospital IQR Program.

We are proposing to calculate the SSI measure rate for purposes of the FY 2015 PCHQR Program using data from the first quarter (Q1) of calendar year (CY) 2014. We recognize that using data from only one quarter may not provide a complete picture of the quality of care provided at a PCH. However, our intent is to align the PCHQR reporting timeline with the reporting timeline used by the Hospital IQR Program as well as to leverage current IT infrastructure to minimize cost and burden.

We are proposing to calculate the SSI measure rate for purposes of the FY 2016 program using data from the last three quarters (Q2, Q3, and Q4) of CY 2014, and we are proposing to calculate the SSI measure rate for purposes of the

FY 2017 program using data from all four quarters (Q1, Q2, Q3, and Q4) of CY 2015. The table below outlines the proposed reporting periods and submission timeframes for FY 2015, FY 2016, and FY 2017.

PROPOSED SSI MEASURE REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR FYS 2015, 2016 AND 2017

Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
2015	Q1 2014 events (January 1, 2014–March 31, 2014)	August 15, 2014
2016	Q2 2014 events (April 1, 2014–June 30, 2014)	November 15, 2014
	Q3 2014 events (July 1, 2014–September 30, 2014)	February 15, 2015
	Q4 2014 events (October 1, 2014–December 31, 2014)	May 15, 2015
2017	Q1 2015 events (January 1, 2015–March 31, 2015)	August 15, 2015
	Q2 2015 events (April 1, 2015–June 30, 2015)	November 15, 2015
	Q3 2015 events (July 1, 2015–September 30, 2015)	February 15, 2016
	Q4 2015 events (October 1, 2015–December 31, 2015)	May 15, 2016

We are proposing that PCHs submit the SSI measure data to the CDC through the NHSN database. This is the same procedural/reporting mechanism requirement used for the CLABSI and CAUTI measures we finalized in FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53564). The data submission and reporting procedures have been set forth by CDC for NHSN participation in general and for submission of the SSI measure to NHSN. We refer readers to the CDC's Web site (*http://www.cdc.gov/nhsn/*) for detailed data submission and reporting procedures. After the final submission deadline has passed, we will obtain the PCH-specific calculations that have been generated by the NHSN for the PCHQR Program.

As noted in the table above, we are proposing to adopt a quarterly submission process for the SSI measure that uses a reporting mechanism that is the same as the one finalized for the Hospital IQR Program (77 FR 53539). We have successfully implemented this reporting mechanism in the Hospital IQR Program, and we strongly believe that this type of data submission is the most feasible option because PCHs are accustomed to reporting the CAUTI and CLABSI measures to the NHSN this way.

We welcome public comment on this proposal.

d. Proposed Exceptions to Reporting and Data Submission for HAI Measures (CAUTI, CLABSI, and Proposed SSI)

Last year we finalized policies for the Hospital IQR Program providing exceptions to the reporting and data submission requirements for the CLABSI, CAUTI and SSI measures (77 FR 53539). We implemented these exceptions because we realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting and that that some hospitals may perform so few procedures requiring surveillance under the SSI measure that the data may not be meaningful for *Hospital Compare* or sufficiently reliable to be utilized for payment determination. We also finalized last year the CLABSI and CAUTI measures for PCHQR Program starting with FY 2014 (77 FR 53557) but did not propose to adopt the same exceptions for those measures. This year, we are proposing to adopt the same exceptions to the CLABSI and CAUTI measures for PCHs, which are outlined in CDC's specifications manual, because we realize that some hospitals may not have locations that meet the NHSN criteria. We refer readers to the CDC's specifications manual for more information on location exceptions for the CAUTI [111] and CLABSI.[112]

In addition, as with the Hospital IQR Program, we recognize that some PCHs may perform so few procedures requiring surveillance under the proposed SSI measure that the data may not be meaningful for *Hospital Compare* or sufficiently reliable to be utilized for quality reporting purposes. We are proposing to provide an exception for these PCHs from the reporting requirement in any given year if the PCH performed less than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year.

We are proposing to provide PCHs with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI, and SSI measures. This exception form will be available on QualityNet Web site.

We invite public comment on this proposal.

e. Proposed Reporting and Data Submission Requirements for the Proposed Clinical Process/Oncology Care Measures

We are proposing that PCHs report the proposed clinical process/oncology care measures beginning with January 1, 2015 discharges. We believe that this date will provide enough advance notice for PCHs to prepare to report the measures. We believe that this timeline provides PCHs with sufficient time to prepare to report on the new measures. We are proposing to calculate the clinical process/oncology care measure rates for purposes of the FY 2016 program using data from the first quarter (Q1) of CY 2015, and that PCHs submit aggregated data for each measure for this quarter during a data submission window that will be open from July 1 through August 15, 2015. We are proposing to calculate the clinical process/oncology care measure rates for purposes of the FY 2017 program using data from the last three quarters (Q2, Q3, and Q4) of CY 2015. We are proposing that PCHs submit aggregated data for each measure for each of these quarters during a data submission window that will be open from July 1 through August 15, 2016. We are proposing to calculate the clinical process/oncology care measure rates for purposes of the FY 2018 program using data from the four quarters (Q1, Q2, Q3, and Q4) of CY 2016. We are proposing that PCHs submit aggregated data for each measure for each of these quarters during a data submission window that will be open from July 1 through August 15, 2017. The table below outlines the proposed reporting periods and submission timeframes for FY 2016, FY 2017, and FY 2018 for the proposed clinical process/oncology care measures.

[111] Catheter-Associated Urinary Tract Infection (CAUTI) Event at *http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf.*

[112] Central Line-Associated Bloodstream Infection (CLABSI) Event at: *http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf.*

PROPOSED CLINICAL PROCESS/ONCOLOGY CARE MEASURES—PROPOSED REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR FYS 2016–2018

Program year (FY)	Reporting periods (CY)	Data submission deadlines
2016	Q1 2015 discharges (January 1, 2015–March 31, 2015)	July 1, 2015–August 15, 2015
2017	Q2 2015 discharges (April 1, 2015–June 30, 2015. Q3 2015 discharges (July 1, 2015–September 30, 2015) Q4 2015 discharges (October 1, 2015–December 31, 2015).	July 1, 2016–August 15, 2016
2018	Q1 2016 discharges (January 1, 2016–March 31, 2016). Q2 2016 discharges (April 1, 2016–June 30, 2016 Q3 2016 discharges (July 1, 2016–September 30, 2016). Q4 2016 discharges (October 1, 2016–December 31, 2016).	July 1, 2017–August 15, 2017

For data collection, we are proposing that PCHs submit aggregate-level data through the CMS Web-based Measures Tool. This proposal mirrors the requirements we have finalized for the IPFQR Program (77 FR 53655). PCHs would submit all the data required for a particular program year once annually during the data submission windows we proposed above, and would do so via the PCH section on the QualityNet secure Web site. However, the data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, PCHs will need to track and maintain quarterly records for their data. We refer readers to FY 2013 IPPS/LTCH PPS final rule (77 FR 53655) for more information on the CMS Web-based aggregated data collection tool used in the IPFQR Program, which we are now proposing to also use in the PCHQR Program. We believe that this option is less burdensome to PCHs than patient level reporting.

We also recognize that aggregate level reporting has the potential to result in less accurate measure rates than patient level reporting; however, we have assessed our infrastructure readiness to collect these measures in the PCHQR Program and believe that an aggregate data submission approach is the most feasible approach at this time.

We welcome public comment on the proposed reporting periods and data collection methods/modes for the clinical process/oncology care measures.

f. Proposed Reporting and Data Submission Requirements for the Proposed SCIP Measures

We are proposing that PCHs report the proposed SCIP measures beginning with January 1, 2015 discharges. We believe that this date will provide enough advance notice for PCHs to prepare to report the measures, and our belief is based on the experience gained from collecting the SCIP measures for the Hospital IQR Program.

We are proposing to calculate the SCIP measure rates for purposes of the FY 2016 program using patient-level data from the first quarter (Q1) of CY 2015. We recognize that using data from only one quarter may not provide a complete picture of the quality of care provided at a PCH. However, our intent is to align the PCHQR Program's current reporting timeline with the reporting timeline used by the Hospital IQR Program, as well as to leverage the current IT infrastructure to minimize cost and burden. We are proposing to calculate the SCIP measure rates for purposes of the FY 2017 program using the last three quarters (Q2, Q3, and Q4) of CY 2015. This will allow us to calculate measure rates for FY 2018 using data from all four quarters (Q1, Q2, Q3, and Q4) of CY 2016. The table below outlines the proposed reporting periods and submission timeframes for the FY 2016, FY 2017, and FY 2018 program years.

PROPOSED SCIP MEASURES—PROPOSED REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR FYS 2016–2018

Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
2016	Q1 2015 discharges (January 1, 2015–March 31, 2015)	August 15, 2015
2017	Q2 2015 discharges (April 1, 2015–June 30, 2015)	November 15, 2015
	Q3 2015 discharges (July 1, 2015–September 30, 2015)	February 15, 2016
	Q4 2015 discharges (October 1, 2015–December 31, 2015)	May 15, 2016
2018	Q1 2016 discharges (January 1, 2016–March 31, 2016)	August 15, 2016
	Q2 2016 discharges (April 1, 2016–June 30, 2016)	November 15, 2016
	Q3 2016 discharges (July 1, 2016–September 30, 2016)	February 15, 2017
	Q4 2016 discharges (October 1, 2016–December 31, 2016)	May 15, 2017

We are proposing that PCHs submit patient level data for each of the SCIP measures to CMS through the QualityNet infrastructure. This is the same procedural/reporting mechanism requirement used for collecting Hospital IQR Program SCIP process of care measures. We have successfully implemented this reporting mechanism in the Hospital IQR Program and intend to use the same reporting mechanism to collect data for the PCHQR Program. We are proposing the patient-level data submission approach for the SCIP measures so that we can compare the data being submitted by PCHs with that being submitted by hospitals under the Hospital IQR Program. We also believe that patient-level data will provide us with more granular information that we can use to better assess the quality of care provided at a PCH.

We welcome public comment on the proposed reporting and submission requirements for the proposed SCIP measures and welcome feedback on using patient level versus other types of data submission.

g. Proposed HCAHPS Requirements

The HCAHPS requirements that we are proposing mirror those used for the Hospital IQR Program (77 FR 53537 through 53538). Similarly, we are proposing that PCHs submit HCAHPS data in accordance with the current HCAHPS *Quality Assurance Guidelines* and the quarterly data submission deadlines, both of which are posted at *http://www.hcahpsonline.org*. Like acute care hospitals that submit HCAHPS data under the Hospital IQR Program, we are proposing that PCHs will have approximately 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse, also referred to as the ''HCAHPS data warehouse.''

In order for a PCH to participate in the collection of HCAHPS data, a PCH must either: (1) Contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the PCH's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a vendor provided that the PCH attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: *http://www.hcahpsonline.org*. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site.

We are proposing that a PCH which chooses to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS survey administration.) We would strongly encourage PCHs to submit their entire patient discharge list, excluding patients who had requested ''no publicity'' status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We emphasize that PCHs must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient's MS–DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS *Quality Assurance Guidelines.*

We note that HCAHPS *Quality Assurance Guidelines* require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS Survey, which patients were not eligible, which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS eligibility and sample frame creation.) In addition, the PCH must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the PCH's behalf.

We are proposing that the PCHs obtain and submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the PCH is too small to obtain 300 completed surveys. We are proposing that the absence of a sufficient number of HCAHPS-eligible discharges will be the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. We are proposing that if a PCH obtains fewer than 100 completed surveys, the PCH's scores will be accompanied by an appropriate footnote on the *Hospital Compare* Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess PCH performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that PCHs employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) and the HCAHPS Review and Correction Report that are available. These reports will enable a PCH to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

In order to ensure compliance with HCAHPS survey and administration protocols, we are proposing that PCHs and survey vendors must participate in oversight activities, which will include onsite visits and/or conference calls. During the oversight process, the HCAHPS Project Team will review the PCH's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS Quality Assurance Guidelines. All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We point out that the HCAHPS Quality Assurance Guidelines state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS Survey. We are proposing that if we determine that a PCH is not compliant with HCAHPS program requirements, we may determine that the PCH is not submitting HCAHPS data that meet the requirements of the PCHQR Program. Below is a table outlining the proposed reporting and data submission requirements.

PROPOSED HCAHPS MEASURE—PROPOSED REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR FYS 2016–2018

Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
2016	Q2 2014 discharges (April 1, 2014–June 30, 2014)	October 1, 2014
	Q3 2014 discharges (July 1, 2014–September 30, 2014)	January 7, 2015
	Q4 2014 discharges (October 1, 2014–December 31, 2014)	April 1, 2015
2017	Q1 2015 discharges (January 1, 2015–March 31, 2015)	July 1, 2015
	Q2 2015 discharges (April 1, 2015–June 30, 2015)	October 7, 2015
	Q3 2015 discharges (July 1, 2015–September 30, 2015)	January 6, 2016
	Q4 2015 discharges (October 1, 2015–December 31, 2015)	April 6, 2016
2018	Q1 2016 discharges (January 1, 2016–March 31, 2016)	July 6, 2016
	Q2 2016 discharges (April 1, 2016–June 30, 2016)	October 5, 2016
	Q3 2016 discharges (July 1, 2016–September 30, 2016)	January 4, 2017
	Q4 2016 discharges (October 1, 2016–December 31, 2016)	April 5, 2017

We strongly encourage those PCHs that are currently administering the HCAHPS Survey to continue to do so. We welcome public comment on our proposed HCAHPS requirements for PCHs.

C. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Statutory History

In accordance with section 1886(m)(5) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. Under the LTCHQR Program, for the FY 2014 payment determination and subsequent payment determinations, in the case of an LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by two percentage points.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to the FY 2014 payment determination no later than October 1, 2012.

Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (*http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx*). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance; (b) regular maintenance processes for endorsed quality measures; (c) measures with time limited endorsement for consideration of full endorsement; and, (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (*http://www.qualityforum.org/Measuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx*). Additional information regarding NQF and its measure review processes is available at: *http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx*.

Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made 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 that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a measure(s) that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. General Considerations Used for Selection of Quality Measures for the LTCHQR Program

We seek to promote higher quality and more efficient health care for the citizens we serve. Quality reporting programs, as well as public reporting of that information, furthers such quality improvement efforts. Quality measurement remains the key tool to the success of these programs. Therefore, the selection of only the highest caliber of measures remains a constant priority for CMS.

We seek to adopt measures for the LTCHQR Program that promote better, safer, and more efficient care. Our measure development and selection activities for the LTCHQR Program take into account national priorities, such as those established by the National Priorities Partnership (*http://www.nationalprioritiespartnership.org/*), HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), and the National Quality Strategy (NQS), which is described at: *http://www.healthcare.gov/center/reports/quality03212011a.html*.

We also consider input from the Measure Applications Partnership (MAP) when selecting measures under the LTCHQR Program. The MAP is composed of multi-stakeholder groups convened by our contractor under section 1890 of the Act (currently the NQF). The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of certain categories of quality and efficiency measures as part of a pre-rulemaking process described in section 1890A of the Act. CMS, in turn, must take this input into consideration in selecting those categories of measures, The NQF provided MAP input to CMS in February of 2013, as required under section 1890A(a)(3) of the Act. This input appears at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. Measures proposed for the LTCHQR Program in this proposed rule were measures CMS included under its List of Measures Under Consideration (MUC List) for December 1, 2012,[113] a list CMS must make public by December 1 of each year, as part of the pre-rulemaking process, as described in section 1890A(a)(2). The list is discussed in the MAP Pre-Rulemaking Report available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx* (pp. 170–176). The MAP supported the direction of each of the proposed measures described below, noting the measure concepts as promising for several of them, and requiring further testing and development.

In the absence of NQF endorsement for measures we are proposing for the LTCH setting, or measures that are not fully supported by the MAP for the LTCHQR Program, we are proposing measures that most closely align with the national priorities discussed above and for which the MAP supports the measure concept. Further discussion of why these measures are high-priority in the LTCH setting is included for each proposed measure below.

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.

3. Process for Retention of LTCHQR Program Measures Adopted in Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53637), for the LTCHQR Program, we adopted a policy that once a quality measure is adopted, it is retained for use in subsequent payment determinations, unless otherwise stated. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the LTCHQR Program for a payment determination, this measure will be automatically adopted for all subsequent payment determinations or until we propose to remove, suspend, or

[113] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72363*

replace the measure. For further information on how measures are considered for removal, suspension, or replacement, we refer readers to 77 FR 53614 and 53615.

4. Process for Adopting Changes to LTCHQR Program Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we finalized our policy that if the NQF updates an endorsed measure that we have adopted for the LTCHQR Program 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 LTCHQR Program. Examples of such nonsubstantive changes could be updated diagnosis or procedure codes, medication updates for categories of medications, changes to exclusions to the patient population, or minor changes to definitions. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent. Specific examples of what we might consider substantive are changes in acceptable timing of medication, procedure/process, or test administration, or expansion of the measure to a new setting. The subregulatory process for nonsubstantive changes will include revision of the LTCHQR Program Manual and posting of updates on our LTCH Quality Reporting Program Web site at: *http://www.cms.gov/LTCH-Quality-Reporting/*.

5. Previously Adopted Quality Measures for the FY 2014 and FY 2015 Payment Determinations and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53623), we retained the application of NQF #0678 to the LTCH setting (initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51750)) and adopted updated versions of NQF #0138 and NQF #0139, for the FY 2014 and FY 2015 payment determination and subsequent payment determinations as listed in the following table:

QUALITY MEASURES FINALIZED IN THE FY 2013 IPPS/LTCH PPS FINAL RULE FOR THE FY 2014 AND FY 2015 PAYMENT DETERMINATIONS AND SUBSEQUENT PAYMENT DETERMINATIONS

NQF Measure ID	Measure title
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream Infection (CLABSI) Outcome Measure.
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay).

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53619 through 53623 and 53667 through 53672) for a discussion of the data collection and submission methods for these measures for the FY 2014 payment determination and all subsequent payment determinations and for references to the descriptions and specifications of these measures.

6. Previously Adopted Quality Measures for the FY 2016 Payment Determination and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53636), we adopted two additional quality measures for the LTCHQR Program for the FY 2016 payment determination and subsequent payment determinations, in addition to the three previously adopted measures (CAUTI measure, CLABSI measure, and Pressure Ulcer measure).

Set out below are the quality measures, adopted in FY 2013 IPPS/LTCH PPS final rule, for the FY 2016 payment determination and subsequent payment determinations.

QUALITY MEASURES FINALIZED IN THE FY 2013 IPPS/LTCH PPS FINAL RULE FOR THE FY 2016 LTCHQR PROGRAM PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS

NQF Measure ID	Measure title
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.*
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream Infection (CLABSI) Outcome Measure.*
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay).*
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).**
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel.**

* Adopted for the FY 2014 payment determination and subsequent payment determinations.
** Adopted for the FY 2016 payment determination and subsequent payment determinations.

7. Proposed Revisions to Previously Adopted Quality Measures

We are proposing the following revisions to the quality measures we have previously adopted for the LTCHQR Program.

a. Proposed Revisions for Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) we finalized that for Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), LTCHs should begin to submit data for January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. There is unique seasonality in the timing of influenza activity each year. The CDC, the steward of this measure, notes (*http://www.cdc.gov/flu/about/season/flu-season-2012–2013.htm*) that while influenza activity most commonly peaks in January or February in the United States, it can begin as early as October and can continue to occur as late as

May. The CDC recommends that people get vaccinated against influenza as long as influenza viruses are circulating. Thus, influenza vaccination season usually begins in early fall.

Therefore, we are proposing that, for the LTCHQR Program, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31. Instead of beginning data collection and submission in the middle of the 2013–2014 influenza season, as is the case when reporting begins on January 1, 2014 (as finalized in FY 2013 IPPS/LTCH PPS final rule), we are proposing that data collection begin on October 1, 2014, or when the influenza vaccine becomes available (as defined by the CDC) and continue through March 31, 2015 for the 2014–2015 influenza season. This change will allow LTCHs to collect and report data on influenza vaccination for the entirety of the 2014–2015 influenza season for the FY 2016 payment determination. This change is presented in the following table for the FY 2016 and FY 2017 payment determinations:

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 AND FY 2017 PAYMENT DETERMINATIONS: NQF #0431 INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data collection timeframe	Final submission deadlines	Payment determination
October 1, 2014 (or when the influenza vaccine becomes available)–March 31, 2015	May 15, 2015	FY 2016.
October 1, 2015 (or when the influenza vaccine becomes available)–March 31, 2016	May 15, 2016	FY 2017.

While LTCHs can enter information in CDC's NHSN (*www.cdc.gov/nhsn/*) at any point during the influenza season for NQF #0431, data submission is only required once per year, unlike the other measures finalized for the LTCHQR Program that utilize NHSN (CAUTI measure NQF #0138 and CLABSI measure NQF #0139). For example, LTCHs can choose to submit influenza vaccination data for NQF #0431 on a monthly basis. However, each time an LTCH submits these data, it will be asked to provide a cumulative total of vaccinations for the ''current'' influenza season. Thus, entering this information at the end of the influenza season would yield the same total number of vaccinations. The NHSN system will not track the individual number of vaccinations on a monthly basis, but, rather, will track the cumulative total of vaccinations for the ''current'' influenza season. Also, we note that data collection period for this measure is not 12 months, as with other measures, but is approximately 6 months (October 1 (or when the vaccine becomes available) through March 31). The final deadlines associated with submitting data, approximately 45 days after the end of the data collection timeframe for the FY 2016 payment determination and subsequent payment determinations, remain consistent across measures.

We note that these proposed changes are applicable only to NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel, and not applicable to any other LTCHQR Program measures, proposed or adopted, unless explicitly stated. The specifications for this measure can be found at *http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf*. We invite public comments on our proposal to revise the data collection and reporting timeline for this influenza vaccination measure (NQF #0431) for FY 2016 and FY 2017 payment determination, and subsequent payment determinations.

b. Proposed Revisions for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we finalized that for NQF #0680, Percentage of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay), LTCHs should begin to collect and submit data on January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. This measure, stewarded by CMS, will be collected using items included in the LTCH CARE Data Set (Version 2.01).[114] On February 1, 2013, we solicited public comment on this information collection request through 60-day notice (78 FR 7433 through 7434). On April 12, 2013, we published a 30-day notice to solicit public comment on this information collection request (78 FR 21955 through 21956). Later in 2013, we will release the final data submission specifications and updated LTCHQR Program Manual for the LTCH CARE Data Set (Version 2.01) containing items related to NQF #0680.

In order to allow time and opportunity for LTCHs and vendors to participate in CMS-sponsored training activities pertaining to the implementation of the LTCH CARE Data Set (Version 2.01), as well as time to plan for and incorporate changes into their data collection and entry systems, we are proposing to revise the previously finalized start date of January 1, 2014 for reporting of this measure to April 1, 2014. For CY 2014, data collection will continue through December 31, 2014. We are proposing that data for admissions and discharges for an LTCH during April 1, 2014 through December 31, 2014 will be used for the FY 2016 payment determination. We are also proposing that data for January 1, 2015 through December 31, 2015 (CY 2015) will be used for the FY 2017 payment determination. Thereafter, data for January 1 through December 31 of each year will be used for subsequent payment determinations. The proposed change is illustrated in the table below for the FY 2016 and FY 2017 payment determinations.

[114] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 AND FY 2017 PAYMENT DETERMINATIONS: NQF #0680 PERCENTAGE OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVE THE SEASONAL INFLUENZA VACCINE (SHORT-STAY)

Data collection timeframes	Submission deadlines	Payment determination
April 1, 2014–June 30, 2014	August 15, 2014	FY 2016.
July 1, 2014–September 30, 2014	November 15, 2014.	
October 1, 2014–December 31, 2014	February 15, 2015.	
January 1, 2015–March 31, 2015	May 15, 2015	FY 2017.
April 1, 2015–June 30, 2015	August 15, 2015.	
July 1, 2015–September 30, 2015	November 15, 2015.	
October 1, 2015–December 31, 2015	February 15, 2016.	

Further, we are proposing that while an LTCH's compliance with reporting quality data for NQF #0680 will be based on the calendar year, the measure calculation and public reporting of this measure (once public reporting is instated) will be based on the influenza vaccination season starting on October 1 (or when vaccine becomes available) and ending on March 31 of the subsequent year. For example, while reporting compliance is based on April 1, 2014 through December 31, 2014 for the FY 2016 payment determination, calculation of the measure for public reporting purposes (if this proposal is finalized) will be based on the 2014–2015 influenza vaccination season (October 1, 2014 (or when the vaccine becomes available)–March 31, 2015). Similarly for the following year, reporting compliance will be based on January 1, 2015 through December 31, 2015 for the FY 2017 payment determination, with calculation of the measure for public reporting purposes (if this proposal is finalized) will be based on the 2015–2016 influenza vaccination season (October 1, 2015 (or when vaccine becomes available)–March 31, 2016).

All LTCHs will be required to collect data using the LTCH CARE Data Set.[115] The Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System will remain the data submission mechanism for the LTCH CARE Data Set. Further information on data submission of the LTCH CARE Data Set for the LTCHQR Program Reporting using the QIES ASAP system is available at: *https://www.qtso.com/* and *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

We note that these proposed changes are applicable only to the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) for the LTCHQR Program, and not applicable to any other LTCHQR Program measures, proposed or adopted, unless explicitly stated.

We invite public comments on our proposal to revise the data collection and reporting timeline for this influenza vaccination measure (NQF #0680) for FY 2016 and FY 2017 payment determinations, and subsequent payment determinations.

c. Proposed Revisions for Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750), we adopted an application of NQF #0678 Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) for the FY 2014 payment determination, and retained this application of the measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53619) for the FY 2015 payment determination and subsequent payment determinations. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) for a discussion of the rationale, data collection methods, and submission methods finalized for this measure for the FY 2014 payment determination and subsequent payment determinations, and for references to the description and specifications of this measure.

At the time we completed our work on the FY 2013 IPPS/LTCH PPS final rule, NQF #0678 was not yet NQF-endorsed for use in the LTCH setting and was undergoing ad hoc review at the NQF for expansion to the LTCH setting. As a result, we were only able to adopt an application of the endorsed measure in our FY 2013 IPPS/LTCH PPS final rule. NQF #0678 underwent review for expansion to the LTCH setting by the NQF Consensus Standards Approval Committee (CSAC) on July 11, 2012 and was subsequently ratified by the NQF Board of Directors for expansion to LTCH setting on August 1, 2012.[116] [117] The title of the measure was changed to Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) to reflect this expansion. Updated specifications, reflecting the expansion are available on the NQF Web site at: *http://www.qualityforum.org/QPS/0678*.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we stated that we would continue to use the rulemaking process to adopt changes to measures when NQF review substantially changes the measure. We stated that one example of a substantive change would be the change the NQF makes to a previously endorsed measure when it extends that measure to a new setting. Because NQF #0678 has received endorsement for the LTCH setting, we are now proposing to adopt the updated measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the FY 2015 payment determination and subsequent payment determinations.

This change would not alter the data collection, data submission, or burden finalized in the FY 2013 IPPS/LTCH PPS final rule since there have been no changes to the data elements in the LTCH CARE Data Set (version 1.01), data submission system (QIES ASAP)

[115] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. Available on the Web site at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html.*

[116] National Quality Forum, Consensus Standards Approval Committee Wednesday, July 11, 2012. Transcript. Available on the Web site at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71612*.

[117] Press Release: NQF Removes Time-Limited Endorsement Status for 13 Measures, Measures Now Have Endorsed Status. August 1, 2012. Available on the Web site at: *http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx*

and technical submission specifications for the LTCH CARE Data Set used for this measure. The only difference between the previously finalized measure (NQF #0678 Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay)) and this expanded measure (NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay)) is the change in name and NQF-endorsed expansion of this measure to the LTCH (and IRF) patient population in addition to Skilled Nursing Facility/Nursing Home Short-Stay residents.

We invite public comment on this proposal to adopt NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the LTCHQR Program.

8. Proposed New LTCHQR Program Quality Measures for the FY 2017 and FY 2018 Payment Determinations and Subsequent Payment Determinations

a. Considerations in Updating and Expanding Quality Measures Under the LTCHQR Program for the FY 2017 Payment Determination and Subsequent Payment Determinations

As noted in section IX.C.2. of the preamble of this proposed rule, we consider input from the MAP (*http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*) in selecting measures for the LTCHQR Program. Measures proposed for the LTCHQR Program in this proposed rule were included on CMS's List of Measures under Consideration for December 1, 2012 (MUC List) and discussed in the MAP Pre-Rulemaking Report available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx* (pp. 170–176). MAP supported the direction of each proposed measure.

In the absence of any NQF-endorsed measures for the LTCH setting or measures fully supported by the MAP for LTCHQR Program, we are proposing measures that most closely align with the national priorities discussed in section IX.C.2. of the preamble of this proposed rule and for which there is MAP support for the measure concept. Further discussion of why a particular measure is high priority in the LTCH setting is included for each proposed measure below.

In addition, to the extent practicable, we have for each proposed measure that is not endorsed by the NQF, sought to adopt a measure that has been endorsed or adopted by a national consensus organization, been recommended by multi-stakeholder organizations, and/or been developed with the input of providers, purchasers/payers, and other stakeholders.

b. Proposed New LTCHQR Program Quality Measures for the FY 2017 Payment Determination and Subsequent Payment Determinations

We are proposing the following three new quality measures for the LTCHQR Program to affect the FY 2017 payment determination and subsequent payment determinations:

(1) Proposed Quality Measure #1: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

NQF #1716 is a standardized infection ratio (SIR) of hospital-onset unique blood source MRSA laboratory-identified events among all inpatients in the facility. It was adopted by the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630) for the FY 2015 payment determination, with data collection having begun on January 1, 2013. The measure was developed by the CDC and is NQF-endorsed.

Methicillin-Resistant *Staphylococcus aureus* (*S. aureus*) (MRSA) infections are caused by a strain of *S. aureus* bacteria that has become resistant to antibiotics commonly used to treat these infections. Between 2003 and 2004, an estimated 4.1 million persons in the United States had nasal colonization with MRSA.[118] In addition, in 2005 it is estimated that there were 94,000 invasive MRSA infections in the United States associated with about 18,000 deaths.[119] Currently, there are eight States that have implemented a MRSA Prevention Collaborative.[120] For Medicare populations, MRSA is a source of increased cost, lengths of stay, morbidity and mortality, and can be a consequence of poor quality of care.[121] [122]

Older adults and patients in healthcare settings are most vulnerable to MRSA infections, as these patients have weakened immune systems. LTCHs are characterized by having highly acutely ill patients with multiple comorbidities and longer lengths of stay, thereby making LTCH patients at risk for acquisition of an antibiotic-resistant infection like MRSA infection.[123] According to analysis of ICD–9 codes reported on Medicare claims, LTCHs reported 5,853 cases of MRSA in 2009. Present on admission indicators are not available on LTCH claims; therefore, we are unable to say whether these conditions are present on admission or acquired during the LTCH stay. Therefore, it was not possible to determine which of these infections occurred in the LTCH. However, we note that on the majority of claims, the primary diagnosis is the admitting diagnosis and is considered to be present on admission and therefore, the secondary diagnoses can be assumed to provide a count of conditions that could have been acquired in the LTCH.[124] When it was assumed that a MRSA infection recorded in the primary diagnosis code was likely present on admission and an MRSA infection recorded in the secondary diagnosis code was acquired in the LTCH, there were 5,826 reported cases that may have been acquired in the LTCH.[125] Further, healthcare-associated MRSA infections occur frequently in patients who have invasive devices, such as catheters or ventilators.[126] We included the proposed MRSA measure in the December 1, 2012 MUC list. The MAP

[118] Gorwitz RJ, Kruszon-Moran D, McAllister SK, et al. Changes in the prevalence of nasal colonization with *Staphylococcus aureus* in the United States, 2001–2004. *J Infect Dis* 2008; 197: 1226–34.

[119] Department of Health and Human Services. *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination.* Available at *http://www.hhs.gov/ash/initiatives/hai/infection.html.*

[120] Centers for Disease Control and Prevention. *State Has Implemented a MRSA Prevention Collaborative.* Available at *http://www.cdc.gov/hai/stateplans/states-w-MRSA-collaborative.html*

[121] Centers for Disease Control and Prevention. *People at Risk of Acquiring MRSA Infections.* Available at *http://www.cdc.gov/mrsa/riskfactors/index.html.*

[122] Centers for Disease Control and Prevention. *Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006.* Available at *http://www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf.*

[123] Furuno JP, Hebden JN, Standiford HC, et al. *Prevalence of methicillin-resistant Staphylococcus aureus and Acinetobacter baumannii in a long-term acute care facility. Am J Infect Control 2008;36:468–71.*

[124] Centers for Medicare & Medicaid Services Center for Medicare & Medicaid Innovation. *Hospital Acquired Conditions (HAC)—Report to Congress.* Available at *http://innovation.cms.gov/Files/x/HospAcquiredConditionsRTC.pdf*

[125] Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM–500–T00007). 2011.

[126] Centers for Disease Control and Prevention. *Protect Yourself from MRSA.* Available at *http://www.cdc.gov/features/mrsainhealthcare/.*

supported the direction of this measure.[127]

We are proposing to use the CDC/NHSN reporting and submission infrastructure for reporting of the proposed NHSN Facility-Wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716). CDC/NHSN is the data collection and submission framework currently used for reporting the CAUTI (#0138), CLABSI (#0139), and Influenza Vaccination Coverage Among Healthcare Personnel (#0431) measures. Details related to the procedures for using NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN Facility-Wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) can be found at: *http://www.qualityforum.org/QPS/1716* and *http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf*. For January 2012 – through January 2013, an estimated 42 LTCHs reported laboratory-identified MRSA event data into NHSN.[128] By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We refer readers to section IX.C.9. of the preamble to this proposed rule for more information on data collection and submission. We invite public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2017 payment determination and subsequent payment determinations. (2) Proposed Quality Measure #2: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)

This measure is a standardized infection ratio (SIR) of hospital-onset CDI Laboratory-identified events among all inpatients in the facility, and was adopted by the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630–51631 for the FY 2015 payment determination, with data collection having begun on January 1, 2013. The measure was developed by the CDC and is NQF-endorsed.

Clostridium difficile (*C. difficile*) can cause a range of serious symptoms including diarrhea, serious intestinal conditions, sepsis, and death.[129] In the United States, *C. difficile* is responsible for an estimated 337,000 infections and 14,000 deaths annually.[130] Based on the HHS National Action Plan to Prevent Healthcare-Associated Infections, *C. difficile* rates have increased in recent years.[131] The CDC estimates that *C. difficile* infections cost more than $1 billion in additional health care costs each year.[132] In recent years, *C. difficile* infections have become more frequent, more severe and more difficult to treat. Mortality rates for *C. difficile* infections are highest in elderly patients.[133] Between 1996 and 2009, rates of *C. difficile* infection among hospitalized patients aged 65 years and older increased 200 percent, while deaths related to *C. difficile* increased 400 percent between 2000 and 2007, which is partly attributed to a stronger germ strain.[134] [135] Further, an estimated 90 percent of the *C. difficile*-related deaths occur in patients 65 and older. *C. difficile* is a source of increased costs in patient care, lengths of stay, morbidity and mortality, and can be a consequence of poor quality of care for Medicare patients.[136]

Illness from *C. difficile* most commonly affects older adults in hospitals or in facilities with longer lengths of stay, where germs spread easily, antibiotic use is common, and people are especially vulnerable to infection.[137] Considering *C. difficile* infections are increasing in LTCHs and that the LTCH population is highly vulnerable to *C. difficile* infection, it is important to measure these rates in LTCHs.[138] According to analysis of ICD–9 codes reported on Medicare claims, LTCHs reported 12,282 cases of *C. difficile*-associated disease in 2009. Present on admission indicators are not available on LTCH claims, therefore we are unable to say whether these conditions are present on admission or acquired during the LTCH stay. Therefore, it was not possible to determine which of these infections occurred in the LTCH. However, we note that on the majority of claims, the primary diagnosis is the admitting diagnosis and is considered to be present on admission and therefore, the secondary diagnoses can be assumed to provide a count of conditions that could have been acquired in the LTCH.[139] When it was assumed that a *C. difficile*-associated infection recorded in the primary diagnosis code was likely present on admission and a *C. difficile*-associated infection recorded in the secondary diagnoses code may have been acquired in the LTCH, there were 11,384 reported cases that may have been acquired in the LTCH.[140] In addition, there is evidence that *C. difficile* infections are preventable, and therefore surveillance and measuring infection rates is important to reducing infections and improving patient safety.

Currently, there are three States that require hospitals to report *C. difficile* data to NHSN. Fifteen States have implemented a *C. difficile* Prevention

[127] National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013.* Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738.*

[128] Data from CMS–CDC correspondence on February 1, 2013.

[129] McDonald LC, Coignard B, Dubberke E, et al. Recommendations for surveillance of *Clostridium difficile*–associated disease. *Infect Control Hosp Epidemiol* 2007;28:140–145. Available at: *http://www.jstor.org/stable/pdfplus/10.1086/511798.pdf?acceptTC=true.*

[130] Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at *http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf.*

[131] Department of Health and Human Services. *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination.* Available at *http://www.hhs.gov/ash/initiatives/hai/infection.html.*

[132] Centers for Disease Control and Prevention. *Making Health Care Safer: Stopping C. difficile Infections.* Available at: *http://www.cdc.gov/VitalSigns/HAI/index.html.*

[133] Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at: *http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf.*

[134] Centers for Disease Control and Prevention. *QuickStats: Rates of Clostridium difficile Infection Among Hospitalized Patients Aged ≥65 Years,* by Age Group—National Hospital Discharge Survey, United States, 1996—2009.* MMWR, 60(34); 1171. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6034a7.htm.*

[135] Centers for Disease Control and Prevention. *Making Health Care Safer: Stopping C. difficile Infections.* Available at: *http://www.cdc.gov/VitalSigns/HAI/index.html.*

[136] Dubberke ER, Reske KA, Olsen MA, McDonald LC, Fraser VJ. Short- and long-term attributable costs of *Clostridium difficile*–associated disease in nonsurgical inpatients. *Clin Infect Dis* 2008; 46:497–504. Available at: *http://cid.oxfordjournals.org/content/46/4/497.long.*

[137] Centers for Disease Control and Prevention. *Frequently Asked Questions about Clostridium difficile for Healthcare Providers.* Available at: *http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html.*

[138] Goldstein EJC, Polonsky J, Touzani M, Citron DM. *C. difficile* infection (CDI) in a long-term acute care facility (LTAC). *Anaerobe* 2009; 15:241–243. Available at: *http://www.sciencedirect.com/science/article/pii/S1075996409001176.*

[139] Centers for Medicare & Medicaid Services Center for Medicare & Medicaid Innovation. *Hospital Acquired Conditions (HAC)—Report to Congress.* Available at: *http://innovation.cms.gov/Files/x/HospAcquiredConditionsRTC.pdf.*

[140] Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM–500–T00007). 2011.

Collaborative.[141] The goal for this proposed *C. difficile* measure is to provide a common mechanism (CDC/NHSN) for all LTCHs to report and analyze these data that will inform infection control staff of the impact of targeted prevention efforts. We included the proposed *C. difficile* measure in the December 1, 2012 MUC list. The MAP supported the direction of this measure.[142]

We are proposing to use the CDC/NHSN reporting and submission infrastructure for reporting of the proposed NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Outcome Measure (NQF #1717). CDC/NHSN is the data collection and submission framework currently used for reporting the CAUTI, CLABSI and Influenza Vaccination Coverage Among Healthcare Personnel measures. Similar to the NHSN MRSA Bacteremia Outcome Measure we have proposed above, details related to the procedures for using NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Outcome Measure (NQF #1717) can be found at: *http://www.qualityforum.org/QPS/1717* and *http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf*. For January 2012 through January 2013, an estimated 46 LTCHs reported laboratory-identified *C. Difficile* event data into NHSN.[143] By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program.

We refer readers to section IX.C.9. of the preamble to this proposed rule for more information on data collection and submission. We invite public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2017 payment determination and subsequent payment determinations.

(3) Proposed Quality Measure #3: All-cause Unplanned Readmission Measure for 30 Days Post-Discharge From Long-Term Care Hospitals

LTCHs treat patients who, on average, are hospitalized 25 days or greater with medically complex problems, including prolonged mechanical ventilation or multiple organ failure. In 2011, as reported by MedPAC, about 123,000 Medicare beneficiaries received care for almost 140,000 LTCH stays in roughly 424 LTCHs nationwide, with payments of $5.4 billion.[144] For patients discharged from LTCH settings, the unadjusted rate of readmission to LTCHs and IPPS hospitals in the 30 days after an LTCH discharge was about 26 percent in 2010 and 2011.[145] With such a large proportion of patients being readmitted to an acute level of care (that is, to either an LTCH or to an IPPS hospital), we are interested in monitoring the rates for each facility and reducing rates that are inappropriately high. Thus, we are proposing a risk-adjusted measure of readmission rates, the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals.

This measure will enhance efforts to promote patient safety, reduce healthcare-associated infections, improve coordination of care and care transitions, and reduce healthcare costs. Readmissions are costly to the Medicare program and have been identified as sensitive to improvements in coordination of care and discharge planning for patients.[146] Literature on readmissions is mainly focused on discharges from short-term acute care hospitals. However, processes that may affect readmission rates, such as discharge planning, communications, and coordination, also occur at other inpatient facilities.

While some readmissions are unavoidable, such as those resulting from the inevitable progression of disease or worsening of chronic conditions, readmissions may also result from poor quality of care or inadequate transitions between care settings. Randomized controlled trials in short-stay acute care hospitals have shown that improvement in the following areas can directly reduce hospital readmission rates: Quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20 to 40 percent [147 148 149 150 151 152 153] and a 2011 meta-analysis of randomized clinical trials found evidence that interventions associated with discharge planning helped to reduce readmission rates,[154] illustrating how hospitals may influence readmission rates through best practices.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe it is appropriate to include All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals as a quality measure in the LTCHQR Program. Promoting quality improvements leading to successful transitions of care for patients moving from the LTCH setting to the community or another post-acute care setting, and reducing preventable facility-wide readmission

[141] Centers for Disease Control and Prevention. *State Has Implemented a C. diff Prevention Collaborative.* Available at: *http://www.cdc.gov/hai/stateplans/states-w-CDI-collaborative.html*.

[142] National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013.* Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*.

[143] Data from CMS–CDC correspondence on February 1, 2013.

[144] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy. Available at: *http://www.medpac.gov/documents/Mar13_EntireReport.pdf*, March 2013, see Chapter 11, Long-term care hospital services, pg. 237–257.

[145] RTI analysis of 2010–2011 Medicare MedPAR claims data under CMS contract HHSM–500–2008–00021I.

[146] **Federal Register**, Vol. 76, No. 160, Thursday, August 18, 2011/Rules and Regulations, IV.C.1.a.

[147] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: A randomized trial. Ann Intern Med 2009; 150(3):178–87.

[148] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: The Care Transitions Intervention. J Am Geriatr Soc 2004; 52(11):1817–25.

[149] Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: A randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. J Am Geriatr Soc 2009; 57(3):395–402.

[150] Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: A randomised controlled trial. BMC Public Health 2007; 7:68.

[151] Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009; 4(4):211–218.

[152] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Ann Intern Med 1994; 120(12):999–1006.

[153] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. Jama 1999; 281(7):613–20.

[154] Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB.The Importance of Transitional Care in Achieving Health Reform. Health Affairs 2011; 30(4):746–754.

rates, is consistent with the NQS aims of safer, better coordinated care and lower costs.

Our approach to developing this measure is consistent with NQF-endorsed Hospital-Wide Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789) (*http://www.qualityforum.org/QPS/1789*) finalized for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). We are proposing to use the same statistical approach, the same time window and a similar set of patient characteristics. To the extent appropriate, the proposed LTCH measure is being harmonized with this Hospital-Wide Readmission (HWR) measure [155] and other measures of readmission rates being developed for post-acute care (PAC) settings, including the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Inpatient Rehabilitation Facilities. This reflects MAP recommendations to promote alignment across care settings.[156]

LTCH patients, on average, require long stays at a hospital level of care and need care even after discharge. The setting chosen for placement of the discharged patient, and coordination with caregivers after discharge, are important for the stability of these patients. The rate of readmission to an acute level of care (short or long-term) for such patients will be sensitive to appropriate discharge placement. The All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals assesses return to short-stay acute care hospitals or LTCHs within 30 days of discharge from an LTCH to the community or another care setting of lesser intensity. Patient readmissions are tracked using Medicare FFS claims data for 30 days after discharge, or the date of patient death if the patient dies within 30 days of discharge.

In the Hospital IQR Program, two readmission measurement approaches were taken: (1) Measures related to patients with specific medical conditions, such as heart failure, pneumonia, and acute myocardial infarction,[157] and (2) a hospital-wide measure. In LTCHs, patients tend to be complex and not easily classified into specific condition or procedure types. In addition, LTCHs have relatively small numbers of patients. Even ventilator patients, who are reasonably definable, are not numerous enough to provide good stable indicators of quality. Therefore, a hospital-wide all-cause readmission measure reflects a broader assessment of the quality of care in LTCHs, and may consequently better promote quality improvement and inform consumers about quality care.

In applying the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals, we will follow patients for 30 days after the LTCH discharge date, or date of death if the patient dies within the 30 day post-discharge period, using Medicare FFS claims data. Because patients differ in morbidity and complexity, the measure is risk-adjusted for patient case-mix. The measure also excludes planned readmissions because these are not considered to be indicative of poor quality care on the part of the LTCH.

A model developed by a CMS measure development contractor predicts admission rates while accounting for patient demographics, primary condition in the prior short stay, comorbidities, and a few other patient factors. The use of such risk adjusters will account for case-mix differences that affect patient readmission rates among facilities. While estimating the predictive power of the patient characteristics, the model also estimates a facility specific effect common to patients treated at that facility. Similar to the Hospital IQR Program hospital-wide readmission measure, the proposed LTCHQR Program measure is the ratio of the number of risk-adjusted predicted unplanned readmissions for each individual LTCH, including the estimated facility effect, to the average number of risk-adjusted predicted unplanned readmissions for the same patients treated at a facility with the average effect on readmissions. A ratio above one indicates a higher than expected readmission rate, or lower level of quality, while a ratio below one indicates a lower than expected readmission rate, or higher level of quality. (The construction of the Hospital IQR Program hospital-wide measure and the NQF report may be downloaded from: *http://www.qualityforum.org/Publications/2012/07/Patient_Outcomes_All-Cause_Readmissions_Expedited_Review_2011.aspx*.)

The patient population for the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals includes LTCH patients who:

- Were discharged alive from the LTCH;
- Had 12 months of Medicare Part A, fee-for-service coverage prior to the LTCH stay;
- Had 30 days of Medicare Part A, fee-for-service coverage post discharge;
- Had an IPPS hospital stay within the 30 days prior to the LTCH stay; and
- Were aged 18 years or above when admitted to the LTCH.

As in the Hospital IQR Program hospital-wide readmission measure, patients whose principal diagnosis was cancer and whose treatment was nonsurgical are excluded. Studies of this population that were reviewed for the Hospital IQR Program readmission measure showed them to have a different trajectory of illness and mortality than other patient populations.[158] The measure also excludes patients who were discharged against medical advice.

Readmissions that are not included in the measure are:

- Transfers from an LTCH to another LTCH or IPPS hospital; and
- Readmissions within the 30 day window that are usually considered planned due to the nature of the procedures and principal diagnoses of the readmission.
- LTCH stays that are problematic (for example, overlapping admission and discharge dates).

The planned readmission list for the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals includes the planned procedures specified in the Hospital-Wide All-Cause Unplanned Readmission (HWR) Measure (NQF #1789) used in the Hospital IQR Program, plus other procedures that were determined in consultation with technical expert panel. The list of procedures considered planned may be found in the LTCH Readmissions Measure Specifications file which will be made available for download at the time of release of this proposed rule at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*. In addition to the list of planned

[155] QualityNet. *Hospital-wide All-Cause Unplanned Readmission (HWR) Measure.* Available at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772504318.* As obtained on March 20, 2013.

[156] National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013.* Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738.*

[157] Please refer to 77 FR 53377 and table on 77 FR 53531 for current condition-specific readmission measures used in the Hospital IQR Program, available at: *http://www.gpo.gov/fdsys/pkg/FR-2012-08-31/pdf/2012-19079.pdf.*

[158] National Quality Forum. ''Patient Outcomes: All-Cause Readmissions Expedited Review 2011''. July 2012. pp12

procedures there is a list of diagnoses which, if found as the principal diagnosis on the readmission claim, would indicate that the procedure occurred during an unplanned readmission.

A patient discharged from an LTCH is tracked until one of the following occurs: (1) The 30-day period post-discharge ends; (2) the patient dies; or, (3) the patient is readmitted to an acute level of care (short or long term). If multiple readmissions occur, only the first is considered for this measure. If the first readmission is unplanned, it is counted as a readmission in the measure rate. The occurrence of a planned readmission ends the 30-day window of the index discharge from the LTCH.

Readmission rates are risk-adjusted for patient case-mix characteristics, independent of quality. The risk adjusted model accounts for demographic characteristics, principal diagnosis, co-morbidities, length of stay in the prior IPPS hospital, critical care days in the prior IPPS hospital, number of IPPS hospital stays in the prior year, and the occurrence of various surgery types in the prior IPPS hospital stay.

In modeling LTCH readmissions, all patients are included in a single model, an approach different from the five-cohort approach of the Hospital IQR Program HWR measure, adapted to account for a substantially smaller patient population in the LTCH setting. Separate models for patient types, as was done for the Hospital IQR Program measure, are not feasible. The number of cases is much smaller in the LTCHs than in the IPPS hospitals and patients are generally not as strongly characterized by one major admitting diagnosis or condition. Patient characteristics are captured by diagnoses and prior surgeries, with a marker for prolonged mechanical ventilation also included.

Because there are approximately 120,000 LTCH admissions per year, and approximately 110,000 of those admissions meet the criteria for inclusion, the proposed measure will use a model that merges two years of Medicare claims data. This approach is similar to that used by the Hospital IQR Program condition-specific readmission measures, which use three years of claims data (77 FR 53523). Merging multiple years of data produces more precise estimates of the effects of all the risk adjusters, and increases the sample size associated with each facility. Larger patient samples are better able to meaningfully distinguish facility performance.

Under the exception authority in section 1886(m)(5)(D)(ii) of the Act, we are proposing to use this measure in the LTCHQR Program. This section 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.

In 2012, NQF endorsed two hospital-wide readmission measures, the National Committee for Quality Assurance (NCQA) measure intended for health plans, Plan All-Cause Readmissions (NQF #1768), and CMS' Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789). NQF #1789 is the model for the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospital measure we are proposing. The most recent MAP Pre-Rulemaking Report noted that ''readmission measures are also examples of measures that MAP recommends be standardized across settings, yet customized to address the unique needs of the heterogeneous Post-Acute Care (PAC)/LTC population. MAP has continually noted the need for care transition measures in PAC/LTC performance measurement programs. Setting-specific admission and readmission measures under consideration would address this need.'' [159]

We intend to seek NQF endorsement of the All-cause Readmission Measure for 30 days Post Discharge from Long-Term Care Hospital. As this is a claims-based measure not requiring reporting of new data by LTCHs, this measure will not be used to determine LTCH reporting compliance for the LTCHQR Program. We are proposing to begin reporting feedback to LTCHs on performance of this measure in CY 2016. The initial feedback will be based on FY 2013 and FY 2014 Medicare claims data related to LTCH readmissions. The readmission measure will be part of the LTCH public reporting program once public reporting is instated. We intend to provide details pertaining to public reporting, such as LTCH preview of performance results, of this measure in our future rulemaking.

We invite public comment on these proposals.

c. Proposed New LTCHQR Program Quality Measure for the FY 2018 Payment Determination and Subsequent Payment Determinations

We are proposing one new quality measure, Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), for the LTCHQR Program to affect the FY 2018 payment determination and subsequent payment determinations.

This NQF-endorsed measure is an outcome measure that reports the percentage of residents (or patients if finalized for the LTCH setting) who experienced falls with major injury over a 12 month period. This measure was developed by the CMS and is NQF-endorsed for the Nursing Home/Skilled Nursing Facility setting.

Research indicates that fall related injuries are the most common cause of accidental death in people aged 65 and older, with approximately 41 percent of accidental deaths annually.[160] Rates increase to 70 percent of accidental deaths amongst individuals ages 75 and older.[161] In addition to death, falls can lead to fracture, soft tissue or head injury, fear of falling, anxiety and depression.[162] Research also indicates that approximately 75 percent of nursing facility residents fall at least once a year; twice the rate of their counterparts in the community.[163] Similar data are not available for the LTCH setting. Falls also represent a significant cost burden to the entire health care system, with injurious falls accounting for 6 percent of medical expenses among those age 65 and older.[164]

According to analysis of ICD–9 codes reported on Medicare claims, LTCHs reported 2,567 major injuries due to falls in 2009. Present on admission indicators are not available on LTCH claims, therefore we are unable to say whether these conditions are present on admission or acquired during the LTCH stay. Therefore, it was not possible to

[159] National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013.* Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738.*

[160] Currie LM. Fall and injury prevention. *Annu Rev Nurs Res.* 2006;24:39–74.

[161] Fuller GF. Falls in the elderly. *Am Fam Physician.* Apr 1 2000;61(7):2159–2168, 2173–2154.

[162] Premier Inc. Causes of Falls. 2013. Available: *https://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/causes_of_falls.jsp.*

[163] Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. Ann Intern Med. 1994 Sep 15; 121(6):442–51.

[164] Rubenstein LZ, Powers CM, MacLean CH. Quality indicators for the management and prevention of falls and mobility problems in vulnerable elders (ACOVE). Ann Intern Med. 2001 Oct 16;135(8 Pt 2):686–93.

determine which of these falls occurred in the LTCH. However, we note that on the majority of claims, the primary diagnosis is the admitting diagnosis and is considered to be present on admission and therefore, the secondary diagnoses can be assumed to provide a count of conditions that could have been acquired in the LTCH.[165] When it was assumed that a fall recorded in the primary diagnosis code was likely present on admission and that a fall recorded in the secondary diagnosis code was acquired in the LTCH, there were 2,049 reported injuries that may have been acquired in the LTCH.[166]

According to Morse (2002), 78 percent of falls are anticipated physiologic falls. Anticipated physiological falls are falls amongst individuals who scored high on a risk assessment scale, meaning their risk could have been identified in advance of the fall.[167] To date, studies have identified a number of risk factors for falls.[168 169 170 171 172 173 174 175 176] The identification of such risk factors suggests the potential for health care facilities to reduce and prevent the incidence of falls for their patients.

In light of the evidence discussed above, we are proposing an application of the measure NQF #0674 Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay), for the LTCHQR Program for the FY 2018 payment determination and subsequent payment determinations.

We note that, while NQF #0674 is currently endorsed only for long stay nursing home residents, we believe that an application of this measure would be highly relevant for the LTCH setting. As stated above, many patients receiving care in the LTCH setting are elderly and are at high risk for death and other injuries due to falls. A technical expert panel convened by our measure development contractor discussed potential quality measures for the LTCH setting and stressed that falls with major injury are a major concern in LTCH setting.

In section 1886(m)(5)(D)(ii) of the Act, the exception authority provides that ''[i]n 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 reviewed NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures for falls with major injury in the LTCH setting. We are unaware of any other measures for falls with major injury that have been endorsed or adopted by another consensus organization for the LTCH setting.

Therefore, we are proposing to adopt an application of the NQF-endorsed measure Percent of Nursing Home Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for use in the LTCH setting for the LTCHQR Program under the Secretary's authority to select non-NQF endorsed measures. In the future we will consider applying for NQF review for endorsement of this measure to the LTCH setting as part of the measure expansion process. Additional information regarding NQF #0674, on which our proposed application of the measure will be based, including measure specifications, is available at: *http://www.qualityforum.org/QPS/0674*. The use of different applications of the same quality measure across multiple healthcare settings is also consistent with the 2008 NQF steering committee recommendation that ''in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement.'' Data on NQF #0674 is currently collected and reported on *Nursing Home Compare* as part of the Nursing Home Quality Initiative.[177]

We are proposing that data for the proposed application of NQF #0674 will be collected through the LTCH CARE Data Set,[178] with submission through the QIES ASAP System, as described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53619 through 53621). For more information on LTCHQR Program reporting using the QIES ASAP system, we refer readers to the Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*. We intend to revise the LTCH CARE Data Set to include new items which assess the presence of falls and falls with major injury, should this proposed application of the measure be adopted. These new items will be applied to all LTCH patients and will not distinguish between long stay versus short stay patients since this categorization is not applicable to the LTCH setting.

The items used for the proposed application of the quality measure will be based on the items from the Minimum Data Set (MDS) 3.0, version 1.13.0 (1/17/13) items J1800 (Any Falls Since Admission/Entry or Reentry or Prior Assessment) and J1900A, B and C (Number of Falls (A: with no injury, B: with injury (except major), C with Major injury)) since Admission/Entry or Reentry or Prior Assessment), available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html*. The calculation of the proposed application of the measure will be based on item J1900C, Number of Falls with major injury, since admission. The specifications and data elements for NQF #0674 are available in the MDS 3.0 Quality Measures User's

[165] Centers for Medicare & Medicaid Services Center for Medicare & Medicaid Innovation. *Hospital Acquired Conditions (HAC)—Report to Congress*. Available at *http://innovation.cms.gov/Files/x/HospAcquiredConditionsRTC.pdf*.

[166] Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM–500–T00007). 2011.

[167] Morse, J. M. (2002) Enhancing the safety of hospitalization by reducing patient falls. Am J Infect Control 2002; 30(6): 376–80.

[168] Rothschild JM, Bates DW, Leape LL. Preventable medical injuries in older patients. Arch Intern Med. 2000 Oct 9; 160(18):2717–28.

[169] Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500–95–0062/T.O. #4. Cambridge, MA: Abt Associates, Inc., June 2003.

[170] Avidan AY, Fries BE, James ML, Szafara KL, Wright GT, Chervin RD. Insomnia and hypnotic use, recorded in the minimum data set, as predictors of falls and hip fractures in Michigan nursing homes. J Am Geriatr Soc. 2005 Jun; 53(6):955–62.

[171] Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. J Clin Nurs. 2008 Jan; 17(1):126–34.

[172] Currie LM. Fall and injury prevention. Annu Rev Nurs Res. 2006;24:39–74.

[173] Ellis AA, Trent RB. Do the risks and consequences of hospitalized fall injuries among older adults in California vary by type of fall? J Gerontol A Biol Sci Med Sci. Nov 2001;56(11):M686–692.

[174] Chen XL, Liu YH, Chan DK, Shen Q, Van Nguyen H. Chin Med J (Engl). Characteristics associated with falls among the elderly within aged care wards in a tertiary hospital: a retrospective. 2010 Jul;123(13):1668–72.

[175] Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. Rehabil Nurs. 2010 Jul-Aug;35(4):141–6, 166.

[176] Lee JE, Stokic DS. Risk factors for falls during inpatient rehabilitant Am J Phys Med Rehabil. 2008 May;87(5):341–50; quiz 351, 422.

[177] Nursing Home Quality Initiative, Quality Measures. December 2012. Available: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html*.

[178] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions on updates to the LTCH CARE Data Set.

Manual Version 6.0 available on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html*.

By building on the existing reporting and submission infrastructure for LTCHs, (the LTCH CARE Data Set, which we began using for data collection on October 1, 2012 for the Pressure Ulcer measure), we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We refer readers to section IX.C.9. of the preamble to this proposed rule for more information on data collection and submission.

We invite public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2018 payment determination and subsequent payment determinations.

d. LTCHQR Program Quality Measures and Concepts Under Consideration for Future Years Payment Determinations

We are considering the measures and measure topics in the table below for future years in the LTCHQR Program. We invite public comment on these measures and measure topics, specifically comments regarding the clinical importance, feasibility of data collection and implementation, current use, and usability of data to inform quality improvements in the LTCH setting.

FUTURE MEASURES AND MEASURE TOPICS UNDER CONSIDERATION FOR THE LTCH QUALITY REPORTING PROGRAM

National Quality Strategy Priority: Safety and Healthcare-Associated Infections HAIs.
- Surgical Site Infection.
- Ventilator-Associated Event.
- Ventilator Bundle.

National Quality Strategy Priority: Safety and Healthcare-Acquired Conditions: Avoidable Adverse Events and Serious Reportable Events.
- Manifestations of Poor Glycemic Control.

National Quality Strategy Priority: Effective Clinical Processes.
- Severe Sepsis and Septic Shock: Management Bundle.
- Application of Venous Thromboembolism Prophylaxis (NQF #0371).
- Ventilator Weaning Rate.

National Quality Strategy Priority: Patient Safety.
- Application of Hospital-Based Inpatient Psychiatric Services (HBIPS)-2 Hours of Physical Restraint Use (NQF #0640).
- Application of Percent of Residents Who Were Physically Restrained (Long-Stay) (NQF #0687).

National Quality Strategy Priority: Patient and Caregiver-Centered Care.
- Depression Assessment and Management.
- Functional Change.
- Application of HCAHPS (NQF #0166).
- Application of Pain Management (for example, Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0677)).

National Quality Strategy Priority: Communication and Coordination of Care.
- Application of Medication Reconciliation (NQF #0097).
- Application of Medication Reconciliation Post-Discharge (NQF #0554).
- Reconciled Medication List Received by Discharged Patients (NQF #0646).
- Transition Record with Specified Elements Received by Discharged Patients (NQF #0647).
- Timely Transmission of Transition Record (NQF #0648).

9. Form, Manner, and Timing of Quality Data Submission for the FY 2016 Payment Determination and Subsequent Payment Determinations

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent payment determination, each LTCH submit to the Secretary data on quality measures specified by the Secretary and that such data shall 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 rate year, the Secretary will reduce any annual update to the standard Federal rate for discharges for the hospital during the rate year by two percentage points.

b. Finalized Timeline for Data Submission Under the LTCHQR Program for the FY 2016 Payment Determination

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53637), we finalized the data submission timeline for measures for the FY 2016 payment determination. LTCHs are required to submit data on LTCH admissions and discharges occurring from January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. We adopted this timeframe because we believe this will provide sufficient time for LTCHs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. We also finalized in this rule the quarterly submission deadlines for the FY 2016 payment determination as approximately 45 days after the end of each quarter, as outlined in the table below. This is the date by which all data collected during that quarter must be submitted to CMS for measures using the LTCH CARE Data Set and to CDC for measures using the CDC/NHSN.

FINALIZED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION

Data collection timeframe: CY 2014	Submission deadline
Q1 (January–March 2014).	May 15, 2014.
Q2 (April–June 2014)	August 15, 2014.
Q3 (July–September 2014).	November 15, 2014.
Q4 (October–December 2014).	February 15, 2015.

c. Proposed Timeline for Data Submission for the NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel Measure for the FY 2016 Payment Determination and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) we finalized the adoption of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 payment determination. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636) we also finalized the data collection period for the FY 2016 payment determination to be January 1, 2014 through December 31, 2014. As noted in IX.C.7.a. of the preamble to this proposed rule, there is a unique seasonality in the timing of influenza activity each year. The CDC, the steward of this measure, recommends that people get vaccinated against influenza as long as influenza viruses are circulating. We are proposing that, for the LTCHQR Program, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31of the subseqeuent year for the influenza season. This timeline is consistent with how the NQF specifies this measure. Further details related to the procedures for using the CDC/NHSN for data submission and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at: *http://www.qualityforum.org/QPS/0431* and *http://www.cdc.gov/nhsn/LTACH/hcp-flu-vac/index.html*.

If our proposal in IX.C.7.a. of the preamble to this proposed rule is finalized, LTCHs would be required to report data on the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure from October 1, 2014 or the date on which the vaccine becomes available, whichever occurs first, through March 31, 2015 for the 2014–2015 influenza season for FY 2016 payment determination. We are also proposing that this October (or when vaccine becomes available) through March reporting period for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure would apply to the FY 2017 payment determination and subsequent payment determinations.

d. Proposed Timeline for Data Submission for the NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) Measure for the FY 2016 Payment Determination and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we finalized the adoption of 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. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53637) we also finalized the data collection period for the FY 2016 payment determination to begin January 1, 2014 and continue through December 31, 2014. This measure will be collected using the LTCH CARE Data Set. The LTCH CARE Data Set (version 2.01),[179] proposed data collection instrument for this measure, is currently undergoing OMB review under the Paperwork Reduction Act. We anticipate that the review and approval will be completed by summer 2013.

We generally allow 9–12 months for LTCHs to comply with and integrate the requisite changes to new versions of data sets into their existing IT infrastructure, and to train staff members. Because summer 2013 approval of the LTCH CARE Data Set version 2.01 would only allow 6 months for LTCHs to put plans and procedures into place, we are proposing to move the start date for data collection of this measure to April 1, 2014 instead of the previously finalized start date of January 1, 2014. Data collection and submission of this measure will continue through December 31, 2014 for the FY 2016 payment determination. This proposed change would only affect CY 2014 reporting. We are proposing that for all subsequent payment determinations this measure will be collected on a calendar year basis beginning on January 1 and continuing through December 31 of each year.

[179] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*.

TIMELINE FOR DATA COLLECTION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION

NQF measure ID	Data collection timeframe
NQF #0138*	January 1, 2014–December 31, 2014.
NQF #0139*	January 1, 2014–December 31, 2014.
NQF #0678*	January 1, 2014–December 31, 2014.
NQF #0680	April 1, 2014–December 31, 2014.**
NQF #0431	October 1, 2014 (or when vaccine becomes available)–March 31, 2015.**

*The data collection period for this measure was finalized in the FY 2013 IPPS/LTCH PPS final rule.

**This data collection timeframe for this measure is proposed in this proposed rule.

TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS NQF #0138,* NQF #0139,* NQF #0678*

Data collection timeframe: CY 2014	Final submission deadlines for the LTCHQR program FY 2016 payment determination
Q1 (January–March 2014).	May 15, 2014.
Q2 (April–June 2014)	August 15, 2014.
Q3 (July–September 2014).	November 15, 2014.
Q4 (October–December 2014).	February 15, 2015.

*The data collection period for this measure was finalized in the FY 2013 IPPS/LTCH PPS final rule.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS: NQF #0680 PERCENTAGE OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT STAY)

Data collection timeframe	Final submission deadlines for the LTCHQR program FY 2016 payment determination
April 1, 2014–December 31, 2014.	February 15, 2015.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS: NQF #0431: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data collection timeframe	Final submission deadlines for the LTCHQR program FY 2016 payment determination
October 1 2014 (or when vaccine becomes available)–March 31, 2015.	May 15, 2015.

We invite public comment on these proposed data collection and quarterly submission timeframes for NQF #0680 and NQF #0431 for the FY 2016 payment determination.

e. Proposed Timeline for Data Submission Under the LTCHQR Program for the FY 2017 Payment Determination and Subsequent Payment Determinations

As previously stated, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53637), we finalized the data submission timeline for the FY 2016 payment determination. For the FY 2017 payment determination, we are proposing to require data submission for the LTCHQR Program on all LTCH admissions and discharges occurring January 1, 2015 through December 31, 2015 (CY 2015) with the exception of Influenza Vaccination Among Healthcare Personnel (NQF #0431). We are proposing that the data collection timeframe for this measure (NQF #0431) be in alignment with measure specifications per advisement of the CDC, the steward for this NQF-endorsed measure. Please refer to section IX.C.9.c. of the preamble to this proposed rule for additional information on this measure's timelines.

We note that the All-cause Unplanned Readmission Measure for 30 days Post-Discharge from Long-Term Care Hospitals is a Medicare claims-based measure, therefore no new data need to be collected or reported by the facility. We will use CY 2013 and CY 2014 Medicare claims data to calculate the All-cause Unplanned Readmission Measure for 30 days Post- Discharge from Long-Term Care Hospitals. We are proposing these timeframes because we believe this will provide sufficient time for CMS and LTCHs to put processes and procedures in place to meet the quality reporting requirements under the LTCHQR Program. The proposed data collection reporting periods for the measures applicable to the FY 2017 payment determination are listed in the following table.

PROPOSED TIMELINE FOR COLLECTION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2017 PAYMENT DETERMINATION

NQF measure ID	Data collection timeframe
NQF #0138	January 1, 2015–December 31, 2015.
NQF #0139	January 1, 2015–December 31, 2015.
NQF #0678	January 1, 2015–December 31, 2015.
NQF #0680	January 1, 2015–December 31, 2015.
NQF #0431	October 1, 2015 (or when vaccine becomes available)–March 31, 2016.
NQF #1716	January 1, 2015–December 31, 2015.
NQF #1717	January 1, 2015–December 31, 2015.

For each quarter outlined in the table below during which the LTCHs are required to collect data, we are proposing final submission deadlines occurring approximately 45 days after the end of any given quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow LTCHs to submit data and make any necessary corrections. Set out below is the proposed timeline for submission of LTCHQR Program quality data for the FY 2017 payment determination.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2017 PAYMENT DETERMINATION: NQF #0138, NQF #0139, NQF #0678, NQF #0680, NQF #1716, NQF #1717

Data collection timeframe: CY 2015	Final submission deadlines for the LTCHQR program FY 2017 payment determination
Q1 (January–March 2015).	May 15, 2015.
Q2 (April–June 2015)	August 15, 2015.
Q3 (July–September 2015).	November 15, 2015.
Q4 (October–December 2015).	February 15, 2016.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2017 PAYMENT DETERMINATION: NQF #0431: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data collection timeframe	Final submission deadlines for the LTCHQR program FY 2017 payment determination
October 1 2015 (or when vaccine becomes available)–March 31, 2016.	May 15, 2016.

We invite public comment on this proposal.

f. Proposed Timeline for Data Submission Under the LTCHQR Program for the FY 2018 Payment Determination and Subsequent Payment Determinations

For measures for the FY 2018 payment determination, we are proposing to require data collection on LTCH discharges occurring from January 1, 2016 through December 31, 2016 with the exception of Influenza Vaccination Among Healthcare Personnel (NQF #0431). We are proposing that the data collection timeframe for this measure (NQF #0431) be in alignment with measure specifications per advisement of the CDC, the steward for this NQF-endorsed measure. LTCHs would follow the proposed deadlines presented in the tables below to complete submission of data for each quarter for each proposed measure for the FY 2018 payment determination. For each quarter outlined in the table below during which LTCHs are required to collect data, we are proposing a final submission deadline occurring approximately 45 days after the end of each quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow LTCHs to submit data and make any necessary corrections.

PROPOSED TIMELINE FOR DATA COLLECTION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION

NQF measure ID	Data collection timeframe
NQF #0138	January 1, 2016–December 31, 2016.
NQF #0139	January 1, 2016–December 31, 2016.

PROPOSED TIMELINE FOR DATA COLLECTION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION—Continued

NQF measure ID	Data collection timeframe
NQF #0678	January 1, 2016–December 31, 2016.
NQF #0680	January 1, 2016–December 31, 2016.
NQF #0431	October 1, 2016 (or when vaccine becomes available)–March 31, 2017.
NQF #1716	January 1, 2016–December 31, 2016.
NQF #1717	January 1, 2016–December 31, 2016.
NQF #0674	January 1, 2016–December 31, 2016.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS FOR ALL MEASURES EXCEPT #0431: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data collection timeframe: CY 2016	Final submission deadlines for the LTCHQR program FY 2018 payment determination
Q1 (January–March 2016).	May 15, 2016.
Q2 (April–June 2016)	August 15, 2016.
Q3 (July–September 2016).	November 15, 2016.
Q4 (October–December 2016).	February 15, 2017.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS: NQF #0431: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data collection timeframe	Final submission deadlines for the LTCHQR program FY 2018 payment determination
October 1 2016 (or when vaccine becomes available)–March 31, 2017.	May 15, 2017.

We invite public comment on this proposal.

10. Public Display of Data Quality Measures for the LTCHQR Program

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs under section 1886(m)(5)(C) of the Act available to the public. Section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that a LTCH has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. The statute also requires that the Secretary report quality measures that relate to services furnished in LTCHs on CMS's Internet Web site. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53637) we received and responded to public comment regarding the procedures we could adopt for the public reporting of quality data under the LTCHQR Program.

Currently, we are developing plans regarding the implementation of these provisions. We appreciate the need for transparency into the processes and procedures that will be implemented to allow for public reporting of the LTCHQR Program data and to afford LTCHs the opportunity to preview that data before it is made public. At this time, we have not established procedures or timelines for public reporting of data, but we intend to include related proposals in future rulemaking. We welcome public comment on what we should consider when developing future proposals related to public reporting of quality measures for the LTCHQR Program.

11. Proposed LTCHQR Program Submission Waiver Requirements for the FY 2015 Payment Determination and Subsequent Payment Determinations

Our experience with other quality reporting programs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural or man-made disasters). We define a ''disaster'' as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread or impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an LTCH may have the ability to conduct a full patient assessment, and record and save the associated data either during or before the occurrence of an extraordinary event. In this case, the extraordinary event has not caused the facility's data files to be destroyed, but it could hinder the LTCH's ability to meet the quality reporting program's data submission deadlines. In this scenario, the LTCH would potentially have the ability to report the data at a later date, after the emergency circumstances have subsided. In such cases, a temporary waiver of the LTCH duty to report quality measure data may be appropriate.

In other circumstances of natural or man-made disaster, an LTCH may not have had the ability to conduct a full patient assessment, and record and save the associated data before the occurrence of an extraordinary event. In such a scenario, the facility does not have data to submit to CMS as a result of the extraordinary event. We believe that it is appropriate, in these situations, to grant a full waiver of the reporting requirements.

We do not wish to penalize LTCHs in these circumstances or to unduly increase their burden during these times. Therefore, we are proposing a process, for the FY 2015 payment determination and subsequent payment determinations, for LTCHs to request and for CMS to grant waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the LTCHs. When a waiver is granted, an LTCH will not incur payment reduction penalties for failure to comply with the requirements of the LTCHQR Program. For LTCHQR Program reporting and submission of quality measure data for the FY 2014 payment determination, we will be issuing guidance on the waiver process via the LTCH Quality Reporting Program Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

Under the proposed process for the FY 2015 payment determination and subsequent payment determinations, an LTCH may request a waiver of the requirement to submit quality data for one or more quarters. We are proposing a process that, in the event that an LTCH seeks to request a waiver for quality reporting purposes for the FY

2015 payment determination and subsequent payment determinations, the LTCH may request a waiver for one or more quarters by submitting a written request to CMS. We are proposing that the LTCH compose a letter to CMS that documents the waiver request, with the information below, and submit the letter to CMS via email to the LTCH Quality Waiver mailbox at *LTCHQRP Reconsiderations@cms.hhs.gov*.

We note that the subject of the email must read ''Disaster Waiver Request'' and the letter must contain the following information:

- LTCH CCN;
- LTCH name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- LTCH's reason for requesting a waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the LTCH believes it will be able to again submit LTCH QRP data and a justification for the proposed date.

We are proposing that the letter documenting the disaster waiver request be signed by the LTCH's CEO or CEO designated personnel, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the letter, we would: (1) Provide a written acknowledgement, using the contact information provided in the letter, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) provide a formal response to the CEO or any CEO-designated LTCH personnel, using the contact information provided in the letter, indicating our decision.

This proposal does not preclude us from granting waivers to LTCHs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant a waiver to LTCHs in a region or locale, we are proposing to communicate this decision through routine communication channels to LTCHs and vendors, including, but not limited to, issuing memos, emails, and notices on *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We invite public comment on this proposal.

12. Proposed LTCHQR Program Reconsideration and Appeals for the FY 2015 Payment Determination and Subsequent Payment Determinations

At the conclusion of any given quality data reporting and submission period, we will review the data received from each LTCH during that reporting period to determine if the LTCH has met the quality data reporting requirements. LTCHs that are found to be noncompliant with the reporting requirements set forth for that reporting cycle could receive a reduction in the amount of 2 percentage points to their annual payment update for the upcoming fiscal year.

We are aware that some of our other quality reporting programs, such as the Hospital IQR Program, include an opportunity for providers and suppliers to request a reconsideration of our initial non-compliance determination. We are also aware, for the purposes of the LTCHQR Program, that we will be making compliance determinations for the FY 2014 payment determination in the coming months and there is a need for providers to be able to request a reconsideration if the circumstances warrant. Therefore, to be consistent with other established quality reporting programs and to provide an opportunity for providers to seek reconsideration of our initial non-compliance decision, we are proposing a process that will allow LTCHs to request reconsiderations pertaining to their FY 2015 payment determination and that of subsequent payment determinations.

As part of this process, LTCHs that are non-compliant with the reporting requirements during a given reporting cycle will be notified of that finding. The purpose of this notification is to put the LTCH on notice of the following: (1) That the LTCH has been identified as being non-compliant with the LTCHQR Program's reporting requirements for the reporting cycle in question; (2) that the LTCH will be scheduled to receive a reduction in the amount of two percentage points to the annual payment update for the upcoming fiscal year; (3) that the LTCH may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or that if they were non-compliant, they have a valid and justifiable excuse for this non-compliance; and (4) that the LTCH must follow a defined process on how to file a request for reconsideration, which will be described in the notification.

Upon the conclusion of our review of each request for reconsideration, we will render a decision. We may reverse our initial finding of noncompliance if: (1) The LTCH provides proof of full compliance with all requirements during the reporting period; or (2) the LTCH provides adequate proof of a valid or justifiable excuse for non-compliance if the LTCH was not able to comply with requirements during the reporting period. We will uphold our initial finding of noncompliance if the LTCH cannot show any justification for noncompliance.

We intend to provide details pertaining to the reconsideration process, and the mechanisms related to provider requests for reconsiderations of their payment determination, such as filing requests, required content, supporting documentation, and mechanisms of notification and final determinations on the LTCHQR Program Web site in spring 2013 prior to any LTCH's need for information on the CMS reconsideration process for the FY 2014 payment determination and subsequent payment determinations at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

We invite public comment on the proposed procedures for reconsideration and appeals for FY 2015 payment determination and subsequent payment determinations.

D. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during such rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

We note that section 1886(s)(4)(A)(i) of the Act uses the term ''rate year.'' Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD–9–CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus

making updating rules more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the 12-month period of October 1 through September 30 is referred to as a fiscal year (FY) (76 FR 26435). For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435). For purposes of the discussion below, the term ''rate year'' and ''fiscal year'' both refer to the period beginning October 1 and ending September 30. To avoid any confusion that may be caused by using the term ''rate year'' with respect to the inpatient psychiatric hospitals and psychiatric units quality reporting program, we will use the term ''fiscal year'' rather than ''rate year'' throughout this proposed rule, even when we are referring to statutory provisions that refer to ''rate year.''

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than such payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We generally prefer to adopt NQF-endorsed measures in our reporting programs with some exceptions as provided by law.

For purposes of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the 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. Finally, pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. Such procedures must ensure that a facility has the opportunity to review its data prior to such data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on a CMS Web site.

2. Application of the Payment Update Reduction for Failure To Report for the FY 2014 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and psychiatric units that fail to comply with the quality reporting requirements implemented in accordance with section 1886(s)(4)(C) of the Act, as detailed below. The application of the reduction may result in an annual update for a fiscal year that is less than 0.0 percent and in payment rates for a fiscal year being less than the payment rates for the preceding fiscal year. Pursuant to section 1886(s)(4)(B) of the Act, any such reduction is not cumulative and it will apply only to the fiscal year involved. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53678), we adopted requirements regarding the application of the payment reduction to the annual update of the standard Federal rate for failure to report data on measures selected for the FY 2014 payment determination and subsequent years and added new regulatory text at 42 CFR 412.424 to codify these requirements.

3. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units that are paid under Medicare's IPF PPS (42 CFR 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. For more information on the application of and exceptions to payments under the IPF PPS, we refer readers to section IV. of the November 15, 2004 IPF PPS final rule (69 FR 66926). As we noted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we use the term ''inpatient psychiatric facility'' (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology we have used in the past in our IPF PPS regulations (42 CFR 412.402).

4. Considerations in Selecting Quality Measures

For purposes of the IPFQR Program, section 1886(s)(4)(D)(i) 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. However, the statutory requirements under section 1886(s)(4)(D)(ii) of the Act provide 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.

In implementing the IPFQR Program, our overarching objective is to support the HHS National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care services: *http://www.healthcare.gov/news/reports/quality03212011a.html#na.* Implementation of the IPFQR Program will help achieve the three-part aim by creating transparency around the quality

of care provided at IPFs to support patient decision-making and quality improvement. Over time, the IPFQR Program will help align the goals for quality measurement and improvement at IPFs with those of other providers in the health care system.

We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. We have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646), we will use the following considerations for the development and selection of measures:

- Given the availability of well-validated measures and the need to balance breadth with minimizing burden, the measures should address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy (NQS): clinical care; person- and caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health.
- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible.
- The measure sets should evolve so that they include a focused set of measures appropriate to IPFs that reflects the level of care and the most important areas of service and measures for IPFs as well as measures addressing a core set of measure concepts that align quality improvement objectives across all provider and supplier types and settings.
- Measures should address gaps in quality of inpatient psychiatric care.
- As part of our burden reduction efforts, we continuously seek to weigh the relevance and utility of the measures compared to the burden on IPFs submitting data under the IPFQR Program. As appropriate, we will align our measures with other Medicare and Medicaid quality programs and may consider how we can incorporate data reporting by means of electronic reporting mechanisms, so that the collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature. We consider suggestions and input from technical expert panels (TEPs), convened by CMS contractors, which evaluate IPFQR quality measures for importance, scientific soundness, usability, and feasibility.

We also take into account national priorities and HHS Strategic Plans and Initiatives:

- HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act, which pursues three aims (better care, healthy people, and affordable care) that establish a framework with six identifiable priorities *http://www.healthcare.gov/news/reports/quality03212011a.html#na*:
  - •• Ensuring that each person and family is engaged as partners in their care.
  - •• Promoting effective communication and coordination of care.
  - •• Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
  - •• Working with communities to promote wide use of best practices to enable healthy living.
  - •• Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.
  - •• Making care safer by reducing harm caused in the delivery of care.
- We consider recommendations of the Measures Application Partnership (MAP) for the inclusion of clinical quality measures *http://www.qualityforum.org/MAP/*. The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs.
- HHS is the United States Government's principal department for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. The goals of the HHS Strategic Plan for FYs 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/secretary/about/priorities.html*). HHS will update this strategic plan every 4 years and measure its progress in addressing specific national problems, needs, or mission-related challenges.

HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-Associated Infections in clinical settings and the Partnership for Patients exemplify these programs.

5. Proposed Quality Measures for the FY 2015 Payment Determination and Subsequent Years

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted the following six chart-abstracted IPF quality measures for the FY 2014 payment determination and subsequent years shown in the table below:

PREVIOUSLY ADOPTED IPFQR PROGRAM QUALITY MEASURES BEGINNING WITH THE FY 2014 PAYMENT DETERMINATION

National quality strategy priority	NQF No.	Measure ID	Measure description
Patient Safety	0640	HBIPS–2	Hours of Physical Restraint Use.
	0641	HBIPS–3	Hours of Seclusion Use.
Clinical Quality of Care	0552	HBIPS–4	Patients Discharged on Multiple Antipsychotic Medications.
	0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
Care Coordination	0557	HBIPS–6	Post-Discharge Continuing Care Plan Created.

PREVIOUSLY ADOPTED IPFQR PROGRAM QUALITY MEASURES BEGINNING WITH THE FY 2014 PAYMENT DETERMINATION—Continued

National quality strategy priority	NQF No.	Measure ID	Measure description
	0558	HBIPS–7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge.

We note that, at the time of the finalization of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53258), providers were using ICD–9–CM codes, but as of October 1, 2014 ICD–10–CM codes will be in effect. We do not at this time anticipate that this change will have substantive effects on any measures.

Measures adopted for the IPFQR Program will remain in the quality reporting program for all subsequent years unless specifically stated otherwise (for example, through removal or replacement). We are not proposing to remove or replace any of the previously adopted measures from the IPFQR Program or add any new measures to the IPFQR Program for the FY 2015 payment determination. We believe that keeping the same measures for the FY 2015 payment determination will allow IPFs one additional year during which they could ramp up recordkeeping and improve quality of care on existing measures. We discussed the collection requirements and submission timeframes for these measures in section VIII.F.7. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53658).

b. Proposed New Quality Measures for the FY 2016 Payment Determination and Subsequent Years

We are proposing three new measures for the FY 2016 payment determination and subsequent years for the IPFQR Program. The measures are: (1) SUB–1: Alcohol Use Screening (Submitted for NQF review); (2) SUB–4: Alcohol & Drug Use: Assessing Status After Discharge (Submitted for NQF review); and (3) Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576).

The three proposed measures were included in a publicly available document entitled ''List of Measures under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,'' which is available on the NQF Web site at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. We considered the input and recommendations provided by the MAP in selecting measures to propose for the IPFQR Program at this time. The MAP supported the inclusion of the third proposed measure in the IPFQR Program, and supported the direction of the first two measures, noting that their recommendation is contingent on NQF endorsement. The first two measures were submitted to the NQF in 2012. Currently, the dates for their review have not been established.

The first two of these measures have been developed by and are maintained by The Joint Commission (TJC) (the measure steward) and the third measure has been developed by and is maintained by the National Committee for Quality Assurance (NCQA) (the measure steward). These measures are appropriate for the purposes of assessing the quality of inpatient psychiatric services and align with National Quality Strategy goals of promoting effective prevention and treatment practices (clinical quality of care), and promoting effective communication and coordination of care. Technical specifications for measures ''SUB–1: Alcohol Use Screening'' and ''SUB–4: Alcohol & Drug Use: Assessing Status After Discharge'' can be found on the TJC Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*. Technical specifications for the measure ''Follow-Up After Hospitalization for Mental Illness'' (FUH) (NQF #0576) can currently be found on the NCQA Web site at: *http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf.*

The three proposed measures for FY 2016 and subsequent years are described in more detail below.

(1) SUB–1: Alcohol Use Screening (NQF Review Pending)

Individuals with mental health conditions experience substance use disorders (SUDs) at a much higher rate than the general population. Individuals with the most serious mental illnesses have the highest rates of such disorders. Co-occurring SUDs often go undiagnosed and, without treatment, contribute to a longer persistence of disorders, poorer treatment outcomes, lower rates of medication adherence, and greater impairments to functioning. Accordingly, this proposed measure, and the one immediately following, are intended to assess efforts by IPFs to screen for the most common type of such disorder, alcohol abuse, and to follow up after discharge with individuals who screen positive for alcohol abuse or who received a diagnosis of alcohol or drug disorder during the inpatient stay.

In late 2008, TJC received funding from the Partnership for Prevention and HHS' Substance Abuse and Mental Health Services Administration (SAMHSA) to develop, specify, and test standardized performance measures addressing alcohol screening and cessation counseling. Four alcohol/substance use performance measures were pilot tested in the spring/summer of 2010. The four alcohol/substance use measures (SUB measure set) were approved as a core measure set for use in TJC's accreditation programs (*http://www.jointcommission.org/core_measure_sets.aspx*). The SUB measures can be found in the TJC's Specification Manual for National Hospital Inpatient Quality Measures at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

The SUB–1: Alcohol Use Screening proposed measure assesses the number of patients 18 years of age and older who were screened for alcohol use using a validated screening questionnaire for unhealthy drinking during their inpatient stay, and is reported as a percentage. The numerator includes the number of patients who were screened for alcohol use using a validated screening questionnaire for unhealthy drinking. The denominator includes the number of hospitalized inpatients 18 years of age or older. Higher rates on the measure are indicative of better performance. The measure excludes the following populations: patients younger than 18, cognitively impaired patients, and patients admitted for less than 1 day or greater than 120 days.

This measure is specified for collection through chart abstraction. We are proposing the form, manner, and timing of collection in section IX.D.9. of the preamble of this proposed rule. Full

specifications for this measure are available at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

The SUB–1: Alcohol Use Screening proposed measure meets the measure selection exception requirements for the IPFQR Program under 1886(s)(4)(D)(ii) of the Act as previously discussed in Section 4 (Considerations in Selecting Quality Measures) of this rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topic of substance use disorder screening for the inpatient population.

We invite public comment on this proposed measure.

(2) SUB–4: Alcohol and Drug Use: Assessing Status After Discharge (NQF Review Pending)

The SUB–4: Alcohol and Drug Use proposed measure assesses whether discharged patients are contacted between 7 and 30 days after hospital discharge in order to collect post-discharge follow-up information regarding their alcohol or drug use status. The measure applies to patients 18 years of age or older who screened positive for alcohol abuse, or who received a diagnosis of alcohol or drug disorder during their inpatient stay. The numerator includes the number of discharged patients that are contacted between 7 and 30 days after hospital discharge and follow-up information regarding alcohol or drug use status is collected. The denominator includes the number of discharged patients 18 years of age and older who screened positive for alcohol abuse or who received a diagnosis of alcohol or drug use disorder during their hospital stay. Higher rates on the measure are indicative of better performance.

The following patients are excluded from the measure:

- Patients less than 18 years of age;
- Patients who are cognitively impaired;
- Patients who were not screened or refused to be screened for alcohol use;
- Patients who expired;
- Patients who have a duration of stay less than or equal to 1 day or greater than 120 days;
- Patients who do not screen positive for alcohol abuse;
- Patients discharged to another hospital;
- Patients who left against medical advice;
- Patients discharged to another health care facility;
- Patients discharged to home or other health care facility for hospice care;
- Patients who do not reside in the United States;
- Patients who do not have a phone or cannot provide any contact information;
- Patients discharged to a detention facility, jail, or prison; and
- Patients who are readmitted within the follow-up timeframe.

This measure is specified for collection through chart abstraction. We are proposing the form, manner, and timing of collection in section IX.D.9. of the preamble of this proposed rule. Full specifications for this measure are available at: *https://manual.jointcommission.org/bin/view/Manual/WebHome.*

The SUB–4: Alcohol and Drug Use: Assessing Status After Discharge proposed measure meets the measure selection exception requirements for the IPFQR Program under section 1886(s)(4)(D)(ii) of the Act as previously discussed in section IX.D.4. of the preamble of this proposed rule. Because this measure is not currently NQF-endorsed, we considered other available measures that have been endorsed or adopted by a consensus organization. We found no other feasible and practical measures on the topic of post-discharge alcohol and drug assessment for inpatients who screened positive for substance abuse.

We invite public comment on this proposed measure.

(3) Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576)

Mental illness accounts for a very large disease burden and it is estimated that half of first-time psychiatric patients are readmitted within two years of hospital discharge. Continuity of treatment and appropriate follow-up care and management of chronic diseases, such as mental illnesses, are known to reduce the risk of repeated hospitalizations. Proper follow-up treatment for psychiatric hospitalization can lead to improved quality of life for patients, families, and society as a whole.

The Follow-Up After Hospitalization for Mental Illness measure assesses the percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental health disorders, *and* who *subsequently* had an outpatient visit or an intensive outpatient encounter with a mental health practitioner, or received partial hospitalization services. The measure separately identifies the percentage of patients who received follow-up within 7 and 30 days of discharge. The detailed technical specifications for this measure can be found at: *http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf*.

This measure is specified by the steward for either collection through chart abstraction or calculation using claims/administrative data. We considered using claims/administrative data for patients discharged from IPFs to calculate the measure, and welcome public feedback on this approach. However, we are proposing to collect chart-abstracted data for this measure in order to maintain consistency with the approach used for existing measures in the IPFQR Program, and solicit comment on this proposal. We also considered using claims/administrative data for patients discharged from IPFs to calculate the measure, and would welcome public feedback on this alternative approach. We are proposing the form, manner, and timing of collection in section IX.D.9. of the preamble of this proposed rule.

The Follow-Up After Hospitalization for Mental Illness (FUH) proposed measure meets the measure selection criteria under section 1886(s)(4)(D)(i) of the Act, because it is NQF-endorsed.

We invite public comment on this proposed measure.

In summary, we are retaining all six of the chart-abstracted measures previously adopted for the FY 2014 payment determination and subsequent years. Also, for the FY 2016 payment determinations and subsequent years, we are proposing the addition of three new chart-abstracted measures for the IPFQR Program: (1) SUB–1: Alcohol Use Screening (NQF review pending); (2) SUB–4: Alcohol & Drug Use: Assessing Status After Discharge (NQF review pending); and (3) Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576).

We are proposing the collection requirements for these measures in the ''form, manner, and timing'' section (section IX.D.9.) of the preamble of this proposed rule. The table below lists the previously adopted measures for the FY 2014 payment determination and subsequent years and the proposed additional measures for the FY 2016 payment determination and subsequent years.

PREVIOUSLY ADOPTED AND PROPOSED QUALITY MEASURES FOR THE IPFQR PROGRAM

National quality strategy priority	NQF No.	Measure ID	Measure description
Previously Adopted Measures for the FY 2014 Payment Determination and Subsequent Years			
Patient Safety	0640	HBIPS–2	Hours of Physical Restraint Use.
	0641	HBIPS–3	Hours of Seclusion Use.
Clinical Quality of Care	0552	HBIPS–4	Patients Discharged on Multiple Antipsychotic Medications.
	0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
Care Coordination	0557	HBIPS–6	Post-Discharge Continuing Care Plan Created.
	0558	HBIPS–7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge.
Proposed New Measures for the FY 2016 Payment Determination and Subsequent Years			
Clinical Quality of Care	Review Pending	SUB–1	Alcohol Use Screening.
	Review Pending	SUB–4	Alcohol & Drug Use: Assessing Status After Discharge.
	0576	FUH	Follow-Up After Hospitalization for Mental Illness.

We invite public comment on these proposals.

c. Maintenance of Technical Specifications for Quality Measures

We will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism known as the Web-based Measure Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We will maintain the technical specifications for the quality measures by updating this manual periodically and including detailed instructions for IPFs to use when collecting and submitting data on the required measures. These updates will be accompanied by notifications to IPFQR Program participants, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53652), we stated that the NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. 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 we have adopted for the IPFQR Program so that these measures remain up-to-date.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653), we adopted a policy to use a subregulatory process to make nonsubstantive updates to NQF-endorsed measures used for the IPFQR Program. We also stated that we expected to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis, and provided examples of the types of changes that would fall into each category.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. As stated in the FY 2013 IPPS/LTCH PPS final rule, we will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also will post the updates on the QualityNet Web site at *https://www.QualityNet.org*. We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the IPFQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: Changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We believe that the policy finalized in the FY 2013 IPPS/LTCH PPS final rule adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed IPFQR Program measures in the most expeditious manner possible, while

preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the IPFQR Program.

6. Proposed Request for Voluntary Information—IPF Assessment of Patient Experience of Care

As indicated previously, we strive to address each of the six priorities of the HHS National Quality Strategy in our quality reporting programs. One priority area currently unaddressed in the IPFQR Program is that of patient and family engagement and experience of care. We included on our ''List of Measures under Consideration for December 1, 2012,'' the measure ''Inpatient Consumer Survey of Inpatient Behavioral Healthcare Services'' (NQF #0726). The MAP provided input on this measure supporting its inclusion in the IPFQR Program.

We believe that while the specific survey instrument incorporated in that measure addressed an important area of quality care, we are not proposing to adopt the measure at this time because of several issues. These issues include potential reporting and information collection burdens in a new program, and compatibility with the content and format of other similar CMS beneficiary surveys. We intend to pursue the adoption of a standardized measure of patient experience of care for the IPFQR Program in the near future.

In an effort to proceed cautiously with the selection of an assessment instrument and collection protocol, we are instead proposing at this time to collect information from IPFs participating in the IPFQR Program regarding whether the IPF assesses patient experience of inpatient behavioral health services using a standardized instrument (Yes/No). We will also ask those IPFs that answer ''Yes'' to indicate the name of the survey that they administer. Submission of this information is completely voluntary and would not in any way affect an IPF's FY 2016 payment determination.

We will use information we collect from this request for voluntary information to assess readiness of IPFs to report patient experience of care measure data in the IPFQR Program. We intend to propose to make this request for voluntary information a mandatory measure in future rulemaking.

Section IX.D.9. of the preamble of this proposed rule, which covers the form, manner, and timing of data submissions, includes our proposal for collection requirements that would apply to any information IPFs voluntarily submit. Section X.D.9. also includes more information about the request for voluntary information.

We welcome comments on this approach as well as recommendations concerning future measurement of this domain, including recommendations of specific instruments for surveying patient and family engagement and experience of care in inpatient psychiatric settings.

7. Request for Recommendations for New Quality Measures for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the inpatient psychiatric setting. Therefore, through future rulemaking, we intend to propose new measures that will help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services, through the widespread dissemination and use of performance information.

We plan to continue developing a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in IPFs. Accordingly, we are soliciting recommendations concerning future measures to assess the domains that arise from the six NQS priorities: Clinical care; person- and caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health. This approach will enhance better psychiatric care while bringing the IPFQR Program in line with other established quality reporting and performance improvement programs who also aim to align with the NQS priorities such as the Hospital Inpatient Quality Reporting (IQR) Program, the Hospital Outpatient Quality Reporting (OQR) Program, the Hospital Value-Based Purchasing (VBP) Program, the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and other CMS quality programs. Recommendations for consideration of individual measures should address the importance of the measure, its scientific evidence, its relevance for quality improvement, and the feasibility of collection and reporting.

We welcome all recommendations related to any of the identified domains. However, we are particularly interested in measure and domain recommendations concerning: (1) Inpatient psychiatric treatment and quality of care of geriatric patients and other adults, adolescents, and children; (2) quality of prescribing for antipsychotics and antidepressants; (3) readmissions; (4) access to care; (5) screening for suicide and violence; and (6) screening and treatment for nonpsychiatric, comorbid conditions for which patients with mental or substance use disorders are at higher risk. In addition, we seek recommendations on any other measures related to patient experience of care and overall quality of care for IPFs.

We welcome public comment on considerations of additional measure topics for the IPFQR Program in future rulemaking.

8. Proposed Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making the data submitted under the IPFQR Program available to the public. Such procedures shall ensure that an IPF has the opportunity to review the data that is to be made public with respect to the IPF prior to such data being made public. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), we finalized our procedures for the FY 2014 payment determination and subsequent years regarding public display. We previously finalized that the data collected under the IPFQR program would be displayed on a CMS Web site and that public display would begin in the first quarter of the calendar year following the respective payment determination year (77 FR 53654). Last year, we also finalized a 30-day preview period that would allow IPFs to review their data before it became public. The previously finalized preview period is September 20 through October 19 of the respective payment determination year (77 FR 53654).

We are proposing to change our finalized policies, however, in an attempt to align the IPF preview and display periods with that of the Hospital IQR Program. We are proposing that for the FY 2014 payment determination and subsequent years, we will publicly display the submitted data on a CMS Web site in April of each calendar year following the start of the respective payment determination year. In other words, the public display period for the FY 2014 payment determination would

be April 2014; the public display periods for the FY 2015 and FY 2016 payment determinations would be April 2015 and April 2016 respectively, and so forth.

Accordingly, we also propose that the preview period for the FY 2014 payment determination and subsequent years be modified to 30 days approximately twelve weeks prior to the public display of the data. This is to align with the Hospital IQR Program's preview and display periods and, as a result, reduce burden to facilities. Below, please find a table that displays the new proposed public display timeline. Although we have listed the public display timeline only for the FYs 2014 through 2016 payment determinations, this policy applies to the FY 2014 payment determination and subsequent years.

PROPOSED PUBLIC DISPLAY TIMELINE FOR THE FY 2014 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Payment determination year (fiscal year)	Reporting period (calendar year)	Public display (calendar year)
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012) Q1 2013 (January 1, 2013–March 31, 2013)	April 2014.
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013) Q4 2013 (October 1, 2013–December 31, 2013)	April 2015.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014) Q3 2014 (July 1, 2014–September 30, 2014) Q4 2014 (October 1, 2014–December 31, 2014)	April 2016.

We welcome public comment on these proposals.

9. Form, Manner, and Timing of Quality Data Submission for the FY 2014 Payment Determination and Subsequent Years

a. Background

Section 1886(s)(4)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent year, each IPF submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(s)(4)(A) of the Act, for any IPF that fails to submit quality data in accordance with section 1886(s)(4)(C) of the Act, the Secretary will reduce any annual update to a standard Federal rate for discharges occurring during such fiscal year by 2.0 percentage points. The complete data submission requirements, submission deadlines, and data submission mechanism, known as the Web-Based Measure Tool, is posted on the QualityNet Web site at: *http://www.qualitynet.org/*. The Web-Based Measure Tool is an Internet database for IPFs to submit their aggregate data. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53658), we required that IPFs submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool found in the IPF section on the QualityNet Web site (*http://www.qualitynet.org/*).

b. Procedural Requirements

In order to participate in the IPFQR Program, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), we required IPFs to comply with certain procedural requirements. We have aligned these procedural requirements with the Hospital IQR Program to avoid imposing additional burden on providers and to increase efficiencies by virtue of allowing providers to use similar submission requirements across programs. Under these adopted policies, IPFs must—

- Register with QualityNet before the IPF begins reporting, regardless of the method used for submitting the data.
- Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (*http://www.qualitynet.org/*).
- Complete a Notice of Participation (NOP). IPFs that wish to participate in the IPFQR Program must complete an online NOP. Submission of a NOP is an indication that the IPF agrees to participate in the IPFQR Program and public reporting of their measure rates. The timeframe for completing the NOP is between January 1 and August 15 before each respective payment determination year. For example, for the FY 2015 payment determination year, the timeframe for completing the NOP is between January 1, 2014 and August 15, 2014.
- Any IPF that receives a new CMS Certification Number (CCN) on or after the beginning of the respective payment determination year and wishes to participate in the IPFQR Program, but has not otherwise submitted a NOP using the new CCN, must submit a completed NOP no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Quality Improvement Evaluation System to participate in the IPFQR Program.
- Withdrawals from the IPFQR Program will be accepted no later than August 15 before the beginning of each respective payment determination year. We believe the August 15 deadline will give us sufficient time to update payment determinations for each respective year. For example, under current policies, the withdrawal period for the FY 2015 payment determination year is between January 1, 2014 and August 15, 2014. If in a given payment determination year, an IPF withdraws from the program, it will receive a reduction of 2.0 percentage points to that year's applicable percentage increase. Once an IPF has submitted a NOP, it is considered to be an active IPFQR Program participant until such time as the IPF submits a withdrawal form to CMS.
- We determine if an IPF has complied with our data submission requirements by validating each IPF's CCN and their aggregated data submission on the QualityNet Web site.
- IPFs must submit the aggregated numerator and denominator data for all age groups, for all measures, to avoid the 2.0 percentage point reduction.

c. Proposed Submission Requirements for the FY 2016 Payment Determination and Subsequent Years

Currently, IPFs choosing to participate in the IPFQR Program must meet the specific data collection and submission requirements as described on the QualityNet Web site at *http://www.qualitynet.org/* and by TJC, the HBIPS measure steward (77 FR 53655). As we indicated in the FY 2013 IPPS/LTCH PPS final rule, the specifications

for the HBIPS measures can be found on the TJC Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

For the FY 2016 payment determination, we are proposing that, for the proposed chart-abstracted measures listed in the preamble of this proposed rule, participating IPFs meet the same specific data collection and submission requirements when reporting quality measure data. The specifications for the SUB–1 and SUB–4 measures can be found on the TJC Web site at: *http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx*. The specifications for the FUH measure are posted on the NCQA Web site at: *http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf*.

We finalized a policy in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53656) requiring that IPFs submit aggregate data on measures on an annual basis via the Web-Based Measures Tool found in the IPF section on the QualityNet Web site. While this policy applies on an annual basis beginning in FY 2014, it is listed under a sub-heading labeled ''Reporting and Submission Requirements for the FY 2014 Payment Determination'' (77 FR 53655). To avoid reader confusion, we clarify that these reporting and submission requirements finalized in the FY 2013 IPPS/LTCH PPS final rule apply to all subsequent years unless we change our policy through future rulemaking. It is our intent to require that IPFs submit aggregate data on measures on an annual basis via the Web-Based Measures Tool found in the IPF section on the QualityNet Web site for the FY 2014 payment determination and subsequent years.

The data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, IPFs will need to track and maintain quarterly records for their data.

With respect to the NCQA's FUH measure, we are proposing all-payer Web-based collection to maintain consistency throughout the measures we have selected for the IPFQR Program. However, we welcome comments for alternative forms of data submission.

As noted earlier, NQF #0726 ''Inpatient Consumer Survey of Inpatient Behavioral Healthcare Services'' is a patient experience measure covering information not measured by existing program measures. While we are not adopting NQF #0726 at this time, we are proposing to request voluntary information about survey administration asking whether the IPF assesses patient experience of inpatient behavioral health services using a standardized instrument. IPFs would only have to provide a ''yes'' or ''no'' response. We will also ask those IPFs that answer ''yes'' to indicate which survey they administer. We are proposing that this information be collected through a Web-based collection tool.

We invite public comment on the proposed submission requirements.

d. Reporting Requirements for the FY 2016 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), we established reporting periods and submission timeframes for the FY 2014, FY 2015, and FY 2016 payment determinations, but we did not require any data validation approach. However, we encouraged the IPFs to use a validation method and conduct their own analysis. Our recommendations remain the same in this proposal. In future years, should we modify the program to require patient-level data, we will consider proposals for an appropriate validation method using rulemaking.

Although in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657) we adopted policies for the FY 2014 payment determination and subsequent years, we only listed quality reporting periods and submission timeframes for the FY 2014, FY 2015, and FY 2016 payment determinations. We explained that the reporting periods for the FY 2014 and FY 2015 payment determinations were 6 and 9 months, respectively, to allow us to achieve a 12 month (calendar year) reporting period for the FY 2016 payment determination. We also indicated that the submission timeframe is between July 1 and August 15 within the same calendar year that marks the beginning of the appropriate payment determination year. We have included this information in the table below.

QUALITY REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR THE FY 2014 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Payment determination (fiscal year)	Reporting period for services provided (calendar year)	Data submission timeframe
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012) Q1 2013 (January 1, 2013–March 31, 2013)	July 1, 2013–August 15, 2013.
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013) Q4 2013 (October 1, 2013–December 31, 2013)	July 1, 2014–August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014) Q3 2014 (July 1, 2014–September 30, 2014) Q4 2014 (October 1, 2014–December 31, 2014)	July 1, 2015–August 15, 2015.

To avoid reader confusion, we are reiterating that the policy we adopted for the FY 2016 payment determination also applies to the FY 2017 payment determination and subsequent years, unless we change it through future rulemaking.

e. Proposed Population, Sampling, and Minimum Case Threshold for the FY 2016 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), for the FY 2014 payment determination and subsequent years, we finalized our policy that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements as specified in TJC's Specifications Manual. We also indicated that the Specifications Manual for the measures is updated at least twice a year (and may be updated more often as necessary), and IPFs must

follow the requirements in the most recent manual, which can be found on the TJC Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome.*

We also finalized our policy that the target population for the quality measures includes all patients, not solely Medicare beneficiaries, to improve quality of care. We believe it is important to require IPFs to submit measures on all patients because quality improvement is of industry-wide importance and should not be focused exclusively on a certain subset of patients. In addition, we need this scope of data in order to be able to assess the quality of care being provided to Medicare beneficiaries.

We also finalized our policy that IPFs that have no data to report for a given measure must enter zero for the population and sample counts. For example, an IPF that has no hours of physical restraint use (HBIPS–2) to report for a given quarter is still required to submit a zero for its quarterly aggregate population for HBIPS–2 in order to meet the reporting requirement. We believe it is important for IPFs to submit data on all measures even when the population size for a given measure is zero or small because it provides us with the opportunity to identify, assess, and evaluate the baseline for the number of cases for each measure in future years. This will also assist us in determining the minimum case threshold for future years in the rule. In cases where the measure rates are calculated based on low caseloads, when the submitted data are publicly displayed on the QualityNet Web site, we will clearly note that the affected measure rates were calculated based on low caseloads that may affect the result.

For the HBIPS measures, which we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), we will continue to apply our finalized policies for population, sampling, and minimum case threshold outlined above. For the measures we have proposed for the FY 2016 payment determination and subsequent years, we are proposing that IPFs follow the sampling and population requirements as specified by the appropriate measure steward as outlined below.

The most recent version of the Specifications Manual, including the sampling and population information for the SUB measures, can be found on the TJC Web site at: *http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx.* We note that IPFs are required to report data only for inpatient discharges treated by the IPF, not for acute care hospital discharges that are not treated and billed by the IPFs.

We are proposing that there will be no sampling required for the FUH measure—IPFs are expected to submit all data. We are proposing that IPFs follow the population requirements outlined at: *http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf.*

We invite public comment on this proposal.

f. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658), we finalized our DACA policy for the FY 2014 payment determination and subsequent years. We stated that IPFs must acknowledge their data accuracy and completeness once annually using a form provided on the QualityNet Web site. To affirm that the data provided to meet the IPFQR Program data submission requirements are accurate and complete to the best of an IPF's knowledge, an IPF is required to submit the DACA form. We will provide a link to this form once IPFs have completed entry of all aggregated measure data. Data submission is not complete until the IPF submits the DACA form. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658), we listed the DACA deadlines for the FY 2014, FY 2015, and FY 2016 payment determinations only, even though our finalized policy was for the FY 2014 payment determination and subsequent years. Set out in the table below are the DACA deadlines we listed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658).

DATA ACCURACY AND COMPLETENESS ACKNOWLEDGMENT (DACA) DEADLINES FOR THE FY 2014 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

Payment determination (fiscal year)	Reporting period for services provided (calendar year)	Data accuracy and completeness acknowledgement deadline
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012) Q1 2013 (January 1, 2013–March 31, 2013)	August 15, 2013.
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013) Q4 2013 (October 1, 2013–December 31, 2013)	August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014) Q3 2014 (July 1, 2014–September 30, 2014) Q4 2014 (October 1, 2014–December 31, 2014)	August 15, 2015.

To avoid reader confusion, we are reiterating that the DACA finalized policies listed above will continue to apply for the FY 2014 payment determination and subsequent years unless and until we change such policies through our rulemaking process. Thus, we will continue with our adopted policy that the deadline for submission of both measure data and the DACA form is no later than August 15 prior to the applicable IPFQR Program payment determination year.

We have summarized the pertinent IPFQR dates in the table below with regard to data reporting periods, submission deadlines, DACA deadlines, and public display periods.

DATA ACCURACY AND COMPLETENESS ACKNOWLEDGMENT (DACA) DEADLINES FOR THE FY 2014 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

Payment determination (fiscal year)	Reporting period for services provided (calendar year)	Submission timeframe	DACA Deadline	Public display
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012) Q1 2013 (January 1, 2013–March 31, 2013)	July 1, 2013–August 15, 2013.	August 15, 2013.	April 2014.
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013) Q4 2013 (October 1, 2013–December 31, 2013)	July 1, 2014–August 15, 2014.	August 15, 2014.	April 2015.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014) Q3 2014 (July 1, 2014–September 30, 2014) Q4 2014 (October 1, 2014–December 31, 2014)	July 1, 2015–August 15, 2015.	August 15, 2015.	April 2016.

Again, we have listed information until FY 2016, but these deadlines apply to the FY 2014 payment determination and subsequent years.

10. Reconsideration and Appeals Procedures for the FY 2014 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53659), we adopted a reconsideration process whereby IPFs can request a reconsideration of their payment update reduction in the event an IPF believes that its annual payment update has been incorrectly reduced for failure to report quality data under the IPFQR Program. We codified the reconsideration procedures that IPFs must follow at 42 CFR 412.434. We instituted an annual reconsideration process similar to the Hospital IQR Program (74 FR 43892). We do not utilize reconsideration policies and procedures related to the Hospital IQR Program validation requirement because the IPFQR Program does not currently include an annual validation requirement for IPFs.

11. Waivers From Quality Reporting Requirements for the FY 2014 Payment Determination and Subsequent Years

In our experience with other quality reporting and/or performance programs, we have noted occasions when participants have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). It is our goal to avoid penalizing IPFs in such circumstances or to unduly increase their burden during these times. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), we adopted a policy that, for the FY 2014 payment determination and subsequent years, IPFs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the IPF may warrant. When waivers are granted, IPFs will not incur payment reductions for failure to comply with the requirements of the IPFQR Program.

Under the process, in the event of extraordinary circumstances not within the control of the IPF, such as a natural disaster, the IPF may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such IPFs would submit a request form to CMS available on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772379030*.

This process does not preclude us from granting waivers or extensions to IPFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect an IPF's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver or extension to IPFs in a region or locale, we will communicate this decision through routine communication channels to IPFs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

12. Electronic Health Records (EHRs)

Under the current and proposed chart-abstracted quality measures, IPFs cannot use EHRs (also referred to as electronic medical records) for data collection because the current and proposed measures will be submitted as aggregate data. However, we encourage IPFs to take steps towards adoption of EHRs that will allow for reporting of clinical quality data from EHRs directly to a CMS repository. We encourage IPFs that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. Although the IPFQR Program is in its initial implementation stages, we recommend that IPFs ensure that their EHR systems accurately capture quality data and that, ideally, such systems provide point-of-care decision support that promotes optimal levels of clinical performance.

In the future, we will continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53660), we responded to public comments on the adoption of EHRs for the IPFQR Program in the future and we again invite public comment on this issue.

E. Electronic Health Record (EHR) Incentive Program and Meaningful Use (MU)

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 EHR technology (CEHRT). Eligible hospitals and critical access hospitals (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.

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 through 54087). The subset of CQMs that we are proposing for voluntary electronic reporting in the Hospital IQR Program in section IX.A.7. of the preamble to this proposed rule is

included in Table 10 of the EHR Incentive Program Stage 2 final rule.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the EHR Incentive Program for the adoption and meaningful use of CEHRT by eligible hospitals and CAHs will encourage the adoption and use of CEHRT for the anticipated electronic reporting of CQMs under the Hospital IQR Program. We expect that the electronic submission of quality data from EHRs under the EHR Incentive Program will provide a foundation for establishing the capacity of hospitals to send, and for CMS to receive, CQMs via CEHRT for certain Hospital IQR Program measures.

2. Proposed Expanded Electronic Submission Period for CQMs

Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting CQMs for and establishing the form and manner of reporting for the EHR Incentive Program, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required. To the extent that CQMs are included in both the Hospital IQR Program and the EHR Incentive Program, we expect that the Hospital IQR Program would transition to using CEHRT rather than manual chart abstraction. The beginning of this transition is described in section IX.A.7. of the preamble to this proposed rule with the proposed voluntary electronic reporting of up to 16 CQMs in the Hospital IQR Program, which are also included in the set of CQMs from which hospitals will report for the EHR Incentive Program beginning in FY 2014 (77 FR 54083 through 54087). By using voluntary electronic reporting in FY 2014 for all 16 of the CQMs proposed under the Hospital IQR Program, hospitals can submit once and fulfill the CQM component of MU as well as the reporting requirement for those 16 CQMs in the Hospital IQR Program.

In the EHR Incentive Program Stage 2 final rule (77 FR 54049–54051), for CQM data that is submitted electronically beginning in 2014, we established the submission period as the two months immediately following the end of the FY (October 1–November 30 for eligible hospitals and CAHs). In response to feedback we have received through various forums, we are proposing to open the submission period for electronically submitted files on January 2. This will allow for better alignment with the Hospital IQR Program. The proposed expanded submission period would allow more flexibility for eligible hospitals and CAHs to start submitting earlier and more frequently, as patients who fit the denominator criteria of the CQMs that the hospitals will submit are discharged. As established in the EHR Incentive Program Stage 2 final rule, the submission period would end on November 30, and eligible hospitals that are demonstrating MU for the first time in the year immediately preceding any payment adjustment year must submit by July 1. This proposal would not change the reporting periods for CQMs established in the EHR Incentive Program Stage 2 final rule (77 FR 54051).

We also are proposing, beginning in FY 2014, to allow eligible hospitals and CAHs that are demonstrating meaningful use for the first time to report CQMs by attestation or through the electronic reporting methods that we establish for the EHR Incentive Program. In the EHR Incentive Program Stage 2 final rule (77 FR 54049 through 54051), we finalized a policy that first-time meaningful EHR users would be required to report CQMs through attestation. This proposal would change that policy to allow more flexibility for eligible hospitals and CAHs to choose between reporting by attestation or electronically in their first year of MU. For further explanation of reporting CQMs by attestation or electronically under the EHR Incentive Program, we refer readers to the discussion of reporting methods in the EHR Incentive Program Stage 2 final rule (77 FR 54087 through 54089). Regardless of the reporting method selected, however, the July 1 deadline for avoiding the Medicare payment adjustments will remain the same, as established in the EHR Incentive Program Stage 2 final rule (77 FR 54049 through 54051). We emphasize that to avoid a payment adjustment under Medicare, eligible hospitals demonstrating MU for the first time in the year immediately preceding any payment adjustment year must complete their submission of CQM data by July 1.

We note although reporting CQM data by attestation would still be an option for first-time meaningful users under the EHR Incentive Program, it would not fulfill any Hospital IQR Program requirements. We welcome public comment on this proposal.

3. Quality Reporting Data Architecture Category III (QRDA–III) Option in 2014

In the EHR Incentive Program Stage 2 final rule (77 FR 54088), we finalized two options for eligible hospitals and CAHs to electronically submit CQMs beginning in FY 2014 under the Medicare EHR Incentive Program. Option 1 was to electronically submit aggregate-level CQM data using QRDA–III. Option 2 was to electronically submit using a method similar to the Hospital IQR Program electronic reporting pilot, which uses QRDA–I (patient-level data). We also stated that, consistent with section 1886(n)(3)(B)(ii) of the Act, in the event the Secretary does not have the capacity to receive CQM data electronically, eligible hospitals and CAHs that are beyond their first year of meaningful use may continue to report aggregate CQM results through attestation.

We have determined that the electronic submission of aggregate-level data using QRDA–III will not be feasible in 2014 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. Thus, for the 2014 reporting period under the Medicare EHR Incentive Programs, eligible hospitals and CAHs would have the option to continue to report aggregate CQM results through attestation. We will reassess this policy for the 2015 and future reporting periods. We note that submissions of aggregate CQM data via attestation would not satisfy the reporting requirements for the Hospital IQR Program. We also note that this proposed policy does not apply to the Medicaid EHR Incentive Program. Therefore, the States may still require the submission of QRDA–III files to fulfill the CQM reporting requirements for hospitals that participate in the Medicaid EHR Incentive Program.

As described in section IX.A.9.d. of the preamble of this proposed rule, the Hospital IQR Program intends to continue its policy to accept patient-level data as it transitions to electronic reporting. In order to remain aligned with the Hospital IQR Program, and because over 82 percent of hospitals that participate in the Hospital IQR Program are already meaningful users, we strongly recommend that hospitals that are eligible to participate in both programs electronically submit the 16 CQMs identified by the Hospital IQR Program in section IX.A.7. of the preamble of this proposed rule. We believe that keeping the two programs aligned will ultimately reduce reporting burden for hospitals. We believe that the proposed extension of the submission period that we are proposing in section IX.E.2. of the preamble of this proposed rule will also help the electronic submission process for hospitals. We welcome public comment on this proposal.

4. Case Number Threshold Exemption—Proposed Requirements Regarding Data Submission

In the EHR Incentive Program Stage 2 final rule (77 FR 54080), we established a case number threshold exemption policy for eligible hospitals and CAHs that experience a low volume of cases addressed by certain CQMs, and stated that hospitals seeking an exemption under the policy must submit aggregate population and sample size data in the same manner as required in the Hospital IQR Program. Our intent was to reduce the burden on hospitals and CAHs that participate in both programs so they would only need to submit this information once. However, we have determined that this information could be captured in QualityNet for both the EHR Incentive Program and the Hospital IQR Program during the process of electronically submitting CQMs. We are proposing to require that the aggregate population data be entered into QualityNet (for EHR-based reporting) during the process of electronically submitting CQMs. We note that sample size data are not required for electronically submitted CQMs.

We note that, in general, the submission deadline for the aggregate population data is the same as the submission deadline for CQMs (November 30). For eligible hospitals in their first year of demonstrating MU, the aggregate population data would need to be submitted no later than July 1 for hospitals that seek to invoke the case number threshold exemption, as this data would be needed to determine whether the eligible hospital met the CQM reporting requirements for MU.

X. Proposed Change to the Medicare Hospital Conditions of Participation (CoPs) Relating to the Administration of Pneumococcal Vaccines

Among the regulations at 42 CFR Part 482 governing the Conditions of Participation (CoPs) for hospitals to participate in the Medicare program, we have established a condition for Nursing Services under § 482.23. Included in the standards for the nursing services condition is a standard for the preparation and administration of drugs. Section § 482.23(c)(3) contains the following provision: ''With the exception of influenza and pneumococcal *polysaccharide* [emphasis added] vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).'' At the time that this CoP standard was originally promulgated (October 2, 2002), and for several years thereafter, the pneumococcal polysaccharide vaccine (PPSV or Pneumovax 23®, Merck) was the only pneumococcal vaccine approved for adult use. In developing the original standard, it was not the Agency's intention to specify a particular type or brand of pneumococcal vaccine. Instead, the Agency wanted to allow hospitals the flexibility to have a policy where nurses could administer influenza and pneumococcal vaccines without a prior practitioner order and only after assessing patients for any contraindications to the vaccines being administered.

However, we recently became aware of another pneumococcal vaccine (pneumococcal conjugate vaccine (PCV) or Prevnar 13®, Pfizer), which received FDA approval for adult use in December 2011. We believe that the availability of another FDA-approved pneumococcal vaccine may have the potential for causing confusion in the hospital community at large by our use of the term ''polysaccharide'' as a distinguisher for the pneumococcal vaccine in the hospital CoP standard. Indeed, it has come to our attention that some hospitals may be using only the polysaccharide type of pneumococcal vaccine because they believe they are not permitted under the CoPs to stock and use any other type of pneumococcal vaccine. We believe the proposed change would allow for the inclusion of all pneumococcal vaccines approved for use now and in the future. With two types of pneumococcal vacccines currently approved for use with adults, we also believe that patient access to the pneumococcal vaccine would potentially improve because hospitals would now possess the freedom and flexibility to choose which type of pneumococcal vaccine(s) it will now stock and use.

Therefore, in this proposed rule, we are proposing to amend the regulatory language at § 482.23(c)(3) to delete the term ''polysaccharide''. This proposed deletion would allow a hospital to include any type of pneumococcal vaccine as part of its physician-approved policy for administration by nurses without a prior practitioner order, provided the vaccine has been approved by the FDA for the patient population to which the hospital intends to administer it. In addition, this proposed change would give hospitals the added flexibility to include the administration of any pneumococcal vaccines that are approved in the future by the FDA for administration under this CoP standard.

XI. 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 2013 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2014 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

XII. 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*. Data files and the cost for each file, if applicable, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request, along with a company check or money order (payable to CMS–PUF) to cover the cost of the data files requested, to the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2010 Medicare cost reports used to create the proposed FY 2014 prospective payment system wage index. Multiple versions of this file are created each year. For a complete

schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.J. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2013	2010	2014
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008
2006	2003	2007
2005	2002	2006
2004	2001	2005

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2014 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the 2010 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.J. of the preamble of this proposed rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2014 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2014 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2014 IPPS Update.

5. FY 2014 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a historical list of Metropolitan Statistical Areas (MSAs).

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2014 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp* and Compact Disc (CD).

File Cost: $100.00 per year.

7. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's or the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 1985 through FY 2014.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. There are two versions of this file as published in the **Federal Register**.

- Notice of proposed rulemaking.
- Final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 2005 through FY 2014 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage*.

Periods Available: FY 1994 through FY 2014 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2014 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-based Statistical Area (CBSA). The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2014 IPPS Update.

13. Hospital Readmissions Reduction Program File

This file contains information on the calculation of the Hospital Readmissions Reduction Program payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction, pneumonia and heart failure and the proxy readmissions payment adjustment for each provider included in the program. The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2014 IPPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786–3691.

Commenters interested in discussing any data used in constructing this proposed rule should contact Nisha Bhat at (410) 786–5320.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of this proposed rule discusses 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 2015 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. In FYs 2008, 2009, 2010, 2011, 2012, 2013, and FY 2014, we received 1, 4, 5, 3, 3, 5, and 5 applications, respectively.

3. ICRs for the Proposed Occupational Mix Adjustment to the Proposed FY 2014 Index (Hospital Wage Index Occupational Mix Survey)

Section III.F. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2014 wage index. While the preamble does 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 OCN 0938–0907.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.H.3. of the preamble of this proposed rule discusses proposed revisions to the wage index based on hospital redesignations. As stated in that section, 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 or standardized payment amounts 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. While this requirement is subject to the PRA, the associated burden was previously approved under OCN 0938–0573. However, the information collection expired on December 31, 2011. We are currently seeking to reinstate the information collection and, as required by the PRA, will announce public notice and comment periods in the **Federal Register** separate from this rulemaking.

5. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed under section V.J.3. of this preamble, are not subject to the Paperwork Reduction Act, as stated in section 5506 of the Affordable Care Act.

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 will no longer be using the 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 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 was previously approved under OMB control number 0938–1022.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53666), we stated that, for the FY 2016 payment determinations and subsequent years updates, we are seeking OMB approval for a revised information collection request using the same OMB control number (0938–1022). In the revised request we will add the 5 proposed claims-based measures, if finalized: (1) 30-day risk standardized COPD Readmission; (2) 30-day risk standardized COPD Mortality; (3) 30-day risk standardized Stroke Readmission; (4) 30-day risk standardized Stroke Mortality; and (5) AMI payment per Episode of Care. In addition, we are proposing to remove three chart-abstracted measures: (1) PN–3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital; (2) HF 1: Discharge Instructions; and (3) IMM–1: Immunization for Pneumonia. We are also proposing to remove seven chart-abstracted measures: (1) PN 3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital; (2) HF 1: Discharge Instructions; and (3) IMM 1: Immunization for Pneumonia; (4) AMI–2: Aspirin Prescribed at Discharge; (5) AMI–10: Statin Prescribed at Discharge; (6) HF–3: ACEI or ARB for LVSD; (7) SCIP-Inf–10: Surgery Patients with Perioperative Temperature Management and one structural measure, Systematic Clinical Database Registry for Stroke Care.

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 hospitals. However, we do believe there will be a reduction in the burden associated with the removal of seven chart-abstracted measures and one structural measure. We estimate a reduction in burden associated with data collection for chart-abstracted measures and associated forms. For the FY 2015 payment determination, we estimated that the burden for chart abstracted measures and associated forms for each hospital is 1,900 hours annually. For the FY 2016 payment determination, we estimate the burden to be 1,775 hours annually per hospital. We estimate the total burden for chart abstraction and structural measures for the approximately 3,300 Hospital IQR Program-participating hospitals to be 5.86 million hours.

To support the proposed validation of two additional HAI measures, we also are proposing to add two new HAI Validation Templates for a total of four Validation Templates to be completed by hospitals selected for annual validation. To add these new Templates without increasing burden for the FY 2016 payment determination and future years, we are proposing to randomly assign one-half of the hospitals to submit templates for CLABSI and CAUTI validation and one-half of the hospitals to submit templates for MRSA and CDI validation. We believe this proposal would limit hospital burden because, of the 600 potential, total hospitals selected for annual validation, only up to 300 hospitals would be required to submit for MRSA and CDI validation and up to 300 hospitals would be required to submit for CLABSI and CAUTI validation. We estimate completion of the CLABSI and CAUTI validation templates will take approximately 20 hours each quarter. We estimate completion of the MRSA and CDI validation templates will take approximately 16 hours each quarter. Our proposed validation for the FY 2016 payment determination is for 3 quarters. Therefore, we estimate the total burden for HAI validation to be 60 hours for hospitals validated for CLABSI and CAUTI and 48 hours for hospitals validated for MRSA and CDI. We estimate the total burden for validation templates for the 600 IQR participating hospitals selected for validation to be 32,000 hours.

Utilizing the estimates above, we estimate an overall reduction in burden from the FY 2015 estimate of 6.3 million hours annually to 5.9 million hours annually for the FY 2016 payment determination year. This burden estimate includes both newly added measures and measure sets and those for which we are requesting renewal. It excludes burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate OMB numbers.

Previously, we required hospitals to provide 12 patient charts per quarter per hospital for HAI validation and 15 patient charts per quarter per hospital for validation of clinical process of care measures, for a total of 27 charts per quarter per hospital and 108 charts per year per hospital. For the FY 2016 payment determination and subsequent years, we are proposing to reduce this requirement by 12 charts per hospital per year.

In addition, we are proposing that the requirement to submit patient charts for validation of Hospital IQR Program data may be met by employing either of the following options each quarter: (1) A hospital may submit paper medical records, which is the form in which we have historically requested them; or (2) a hospital may securely transmit electronic versions of medical information for the FY 2016 payment determination and subsequent years. The intent of this proposal is to offer an additional mode through which hospitals may meet the requirement to submit patient charts. To support this proposal, which has the potential to reduce burden, cost, and environmental impact, we also are proposing for the FY 2016 payment determination and subsequent years to reimburse hospitals for submission of electronic versions of medical information.

We are proposing a reimbursement rate of $3.00 per chart taking into account the following considerations:

- Cost estimates are for retrieval of records and not for the maintenance of electronic health records systems, which are supported by CMS by other means.
- The activities associated with submitting an electronic version of a patient medical record include downloading, verifying, and copying records, which must be done for every record separately, and packaging and encrypting CDs or DVDs which must be done only once per DVD or CD sent.
- We assume that an average patient record will be 412 pages in length, that the average capacity of a DVD of 45,000

pages, and that all 27 records submitted in a quarter will fit on one DVD most of the time.

- Based on time and motion studies conducted by our contractor, we estimate that for records of average lengths, the minimum labor time is between 1 and 2 minutes per record.
- To acknowledge that some records may be so large that they require their own DVD, and that some systems may be slower than others, we also estimated a maximum labor of about 12 minutes per record.
- Averaging these two estimates, we achieve an average of less than 7 minutes of labor per record.
- The labor performed can be accomplished by a combination of staff equivalent to a GS–5 administrative secretary and a GS–5 information technologist, earning within the middle range for this grade, which in 2013 was $38,616 per year. Assuming, 2,080 hours in a work year, we achieve an hourly rate of $18.57 per hour.
- Applying OMB Circular A–76, we assumed overhead of 36.25 percent, for a fully burdened labor rate of $25.30 per hour.
- The labor cost associated with each record is $2.95.
- Supply costs are limited to DVDs and packaging. DVDs cost $20 per 100, or 20 cents per DVD. A protective shipping container also costs 20 cents each.
- If a hospital submits all records on the same DVD, supply costs will equal approximately 1.4 cents per DVD. If a hospital submits one DVD per record, supply costs will equal approximately 40 cents per record. Averaging these costs results in 21 cents per record.
- Adding supplies to labor yields a total cost of $3.16 per record.
- Rounding to the nearest whole dollar yields $3.00 per record.

For the FY 2016 payment determination, we also are encouraging hospitals to voluntarily submit 16 measures electronically for the Hospital IQR Program in a manner that would permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare EHR Incentive Program. We estimate that the total burden associated with the electronic quality measure reporting option will be similar to the burden outlined for hospitals in the EHR Incentive Program Stage 2 final rule (77 FR 53968 through 54162). As established in that final rule, beginning in FY 2014, hospitals that are beyond their first year of meaningful use must electronically report a total of 16 clinical quality measures covering at least three domains using CEHRT that has been certified to the 2014 Edition certification criteria.

In accordance with the estimates in the Medicare EHR Incentive Program Stage 2 final rule, we believe it will take a hospital approximately 2 hours and 40 minutes to select, prepare, and electronically submit the 16 quality measures using CEHRT. In addition, in accordance with the Medicare EHR Incentive Program Stage 2 final rule, we believe an individual with commensurate skills will submit electronic clinical quality measures on behalf of the hospital at a rate of approximately $59.00 per hour. Therefore, we believe it will cost a hospital approximately $156.94 ($59.00 x 2.66 hours) to report 16 clinical quality measures electronically in CY 2014 (77 FR 54133). Additional information about the chart abstraction burden is detailed in section XI.B.6. of the preamble to this proposed rule.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section IX.B. of the preamble of this proposed rule, section 1866(k) 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 the FY 2013 IPPS/LTCH PPS final rule, we implemented the PCHQR Program to comply with the statutory mandate, and in an effort to improve the quality of care for inpatient cancer patients. It is our aim and goal to encourage PCHs to furnish high quality care in a manner that is effective and meaningful, while remaining mindful of the reporting burden created by the implementation of this new program. Therefore, we intend to reduce and avoid duplicative reporting efforts, whenever possible, by leveraging existing infrastructure.

In the FY 2013 IPPS/LTCH PPS final rule, for the FY 2014 program year, we adopted five NQF-endorsed quality measures, two of which were developed by the CDC and three of which were developed by the American College of Surgeons' Commission on Cancer (ACoS/CoC) and discussed the information collection requirements for these measures.

Topic	Quality measures
Cancer-Specific Treatments	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage 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)
Healthcare Acquired Infections (HAIs)	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).
	National Healthcare Safety Network (NHSN)Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).

In this proposed rule, we are proposing that PCHs submit data on 1 additional measure beginning with FY 2015 and 13 additional measures beginning with FY 2016 (as listed below), for a total of 19 measures (5 previously adopted plus 14 new measures).

PROPOSED NEW MEASURE BEGINNING WITH FY 2015

Measure domain	NQF Endorsement number	Measure name
Patient Safety	0753	Harmonized Procedure Specific Surgical.

PROPOSED NEW MEASURES BEGINNING WITH FY 2016

Measure domain	NQF Endorsement number	Measure name
Surgical Care Improvement Project (SCIP)	0218	Surgery Patients Who Received Appropriate VTE Prophylaxis within 24 Hrs Prior to Surgery to 24 Hrs After Surgery End Time.
	0284	Surgery Patients on Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker during the Perioperative Period.
	0453	Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 with Day Surgery Being Day Zero.
	0527	Prophylactic Antibiotic Received Within 1 Hr Prior to Surgical Incision.
	0528	Prophylactic Antibiotic Selection for Surgical Patients.
	0529	Prophylactic Antibiotic Discontinued Within 24 Hrs After Surgery End Time.
Clinical Process/Oncology Care	0380	Multiple Myeloma—Treatment with Bisphosphonates.
	0382	Oncology—Radiation Dose Limits to Normal Tissues.
	0383	Oncology: Plan of Care for Pain.
	0384	Oncology: Pain Intensity.
	0390	Prostate Cancer—Adjuvant Hormonal Therapy for High-Risk Patients.
	0389	Prostate Cancer—Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients.
Patient Engagement/Patient Experience of Care	0166	HCAHPS Patient Experience of Care Survey.

We believe that our proposal to require PCHs to submit data on these additional proposed measures will not prove burdensome. PCHs have familiarity with and experience reporting quality data to CMS during the initial year of the PCHQR program. Therefore, we believe that because a majority of PCHs have demonstrated the ability to report these measures, the reporting requirements we are proposing will not significantly impact PCHs.

The anticipated burden on these PCHs consists of the following: training of appropriate staff members on how to use the NHSN for the reporting of the proposed SSI measure, CMS (QualityNet) for the reporting of the proposed SCIP measures, and the CMS Web Measures Tool for the reporting of the proposed clinical process/oncology care measures; the time required for collection and aggregation of data; and the time required for reporting of the data by the PCH's representative; and the time required to participate and collect HCAHPS data. We have taken into account all these elements in our burden calculation.

We estimate that 11 PCHs will submit data on approximately 63,468 cancer cases annually. It will require, on average, 9.5 hours for a PCH to abstract the information from medical records and submit such information for each case. The time required to administer the HCAHPS is likely to be lower than the time for chart abstraction. However, the same method was used to ensure a high-end estimate so that facilities will not experience a higher burden than estimated. In addition, sampling was not considered for this reason. Therefore, this burden represents the ''worst-case scenario'' of what would be required of each facility. Based on these assumptions, we estimate that the annual hourly burden on each PCH for the collection, submission, and training of personnel for submitting all quality measure data would be approximately 54,822 hours.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to adopt three new measures for the FY 2016 Hospital VBP Program, including IMM–2: Influenza Immunization and CAUTI, and the Surgical Site Infection (SSI) measure, stratified as SSI-Colon and SSI-Abdominal Hysterectomy. We also are proposing to adopt CLABSI, a measure that we finalized for FY 2015 but did not readopt at that time.

In addition, we are proposing to adopt the three 30-day mortality measures and the AHRQ PSI composite measure for FYs 2017 through 2019 program determinations.

All 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 (LTCHQR) Program

In section IX.C. of the preamble of the proposed rule, we discuss the requirements for the LTCHQR Program, established by section 1886(m)(5) of the Act, which was added by section 3004 of the Affordable Care Act.

In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of five quality measures for use in the LTCHQR Program for the FY 2016 payment update determination and subsequent payment determinations. These measures are: (1) NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); (2) NHSN Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139); (3) Application of Percent of Residents with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678); (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (5) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) we finalized that for Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), LTCHs should begin to submit data from January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. However, there is unique seasonality in the timing of influenza activity each year. To account for this, we are proposing that, for the LTCHQR

Program, this measure *only* (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1st (or when the vaccine becomes available) through March 31st. This proposed change would allow LTCHs to collect and report data on influenza vaccination for the entirety of the 2014–2015 influenza season for the FY 2016 payment determination. Similarly, this change would allow LTCHs to collect and report data on influenza vaccination for the entirety of future influenza seasons for subseqeuent payment determinations.

While LTCHs can enter information in NHSN at any point during the influenza season for NQF #0431, data submission is only required once per year, unlike the other measures finalized for the LTCHQR Program that utilize CDC/NHSN (CAUTI measure NQF #0138 and CLABSI measure NQF #0139). LTCHs can choose to submit influenza vaccination data on an incremental basis (for example, on a monthly basis), or just once a year. The final deadlines associated with submitting data, approximately 45 days after the end of the data collection timeframe for the FY 2016 payment determination, remain consistent across measures.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we finalized that for NQF #0680, Percentage of Residents or Patients Who Were Assessed and Appropriately Give the Seasonal Influenza Vaccine (Short-Stay), LTCHs should begin to collect and submit data on January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. This measure, stewarded by CMS, will be collected using items included in the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (Version 2.01).[180] On February 1, 2013, we solicited public comment on this information collection request (78 FR 7433 through 7434). On April 12, 2013, we published a 30-day notice to solicit public comment on this information collection request (78 FR 21955 through 21956). Later in 2013, we will release the final data submission specifications and updated LTCHQR Program Manual for the LTCH CARE Data Set (Version 2.01) containing items related to NQF #0680.

In order to allow time and opportunity for LTCHs and vendors to participate in CMS-sponsored training activities pertaining to the implementation of the LTCH CARE Data Set (Version 2.01), as well as time to plan for and incorporate changes into their data collection and entry systems, we are proposing to revise the previously finalized start date of January 1, 2014 for reporting of this measure to April 1, 2014. For CY 2014, data collection will continue through December 31, 2014. We are proposing that data for admissions and discharges for an LTCH during April 1, 2014 through December 31, 2014 will be used for the FY 2016 payment determination. We are also proposing that data for January 1, 2015 through December 31, 2015 (CY 2015) will be used for the FY 2017 payment determination. Thereafter, data for January 1 through December 31 of each year will be used for subsequent payment determinations.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750), we adopted an application of NQF #0678 Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) for the FY 2014 payment determination, and retained this application of the measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53619) for the FY 2015 payment determination and subsequent payment determinations. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) for a discussion of the rationale, data collection methods, and submission methods finalized for this measure for the FY 2014 payment determination and subsequent payment determinations, and for references to the description and specifications of this measure.

At the time we completed our work on the FY 2013 IPPS/LTCH PPS final rule, we were only able to adopt an application of the endorsed measure in our final version of the FY 2013 rule. NQF #0678 was subsequently ratified by the NQF Board of Directors for expansion to the LTCH setting on August 1, 2012.[181, 182] Because NQF #0678 has received endorsement for the LTCH setting, we are now proposing to adopt the updated measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the FY 2015 payment determination and subsequent payment determinations. This measure will continue to be collected using items included in the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (Version 1.01) for CY 2013 and first quarter of CY 2014. Further, starting April 1, 2014, this measure is proposed to be collected using items included in the LTCH CARE Data Set Version 2.01.[183]

The changes we have described to the reporting periods for two measures (NQF #0431 and NQF #0680) and the updated NQF-endorsed pressure ulcer measure (NQF #0678) are not new measures. We do not believe that these changes will result in any additional reporting burden on LTCHs.

In section IX.C.8.b. of the preamble of this proposed rule, we are proposing three additional measures for use in the LTCHQR Program for the FY 2017 payment determination and subsequent payment determinations. These proposed measures are: (1) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-onset *Clostridium Difficile* Infection (CDI) Outcome Measure (NQF #1717); and (3) All-Cause Unplanned Readmission Measure for 30-Days Post Discharge from Long-Term Care Hospitals.

For the FY 2017 payment determination, in addition to the CAUTI, CLABSI, and Influenza Vaccination Coverage among Healthcare Personnel measures, we are proposing that LTCHs would report quality data related to the MRSA and CDI measures to the CDC's NHSN data submission system (*http://www.cdc.gov/nhsn/*). The NHSN is a secure, Internet-based surveillance system that is maintained and managed by CDC.

There are currently approximately 440 LTCHs in operation in the United States and, according to the CDC, over 413 of these LTCHs already submit HAI

[180] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html.*

[181] National Quality Forum, Consensus Standards Approval Committee Wednesday, July 11, 2012. Transcript. Available on the Web site at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71612.*

[182] Press Release: NQF Removes Time-Limited Endorsement Status for 13 Measures, Measures Now Have Endorsed Status. August 1, 2012. Available on the Web site at: *http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx.*

[183] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html.*

data to NHSN. We believe that any burden increase related to complying with the LTCHQR Program requirements for submission of the MRSA and CDI measures will be minimal for those LTCHs that are already familiar with the NHSN submission process, for several reasons. First, these LTCHs will have already completed initial setup and become familiar with reporting data in the NHSN system due to the requirement to report CAUTI and CLABSI measures beginning on October 1, 2012 for the FY 2014 payment determination and continuing reporting for CY 2013 for the FY 2015 payment determination. Second, as of January 2013, there are approximately 42 LTCHs reporting MRSA measure data and approximately 46 facilities reporting *Clostridium Difficile* measure data into NHSN. Third, there has been no change in the registration and training requirements for providers that are already acquainted with the NHSN. Therefore, we believe that most LTCH providers should be very comfortable using the NHSN for continuing with the reporting of data for CAUTI and CLABSI measures for CY 2014 for FY 2016 payment update determination. Further, we believe that by the time (October 1, 2014 or when vaccine becomes available) reporting for NQF #0431 begins for the FY 2016 payment determination, a vast majority of LTCH providers should be very comfortable using the NHSN.

The most significant burden associated with the quality measures is the time and effort associated with collecting and submitting the data on the CAUTI, CLABSI, Influenza Vaccination Coverage among Healthcare Personnel, MRSA, and *Clostridium Difficile* measures to NHSN for LTCHs that are not currently reporting any measures data.

There are currently approximately 440 LTCHs in the United States paid under the CMS LTCH PPS. We estimate that each LTCH will execute approximately 12 NHSN submissions (6 CAUTI events and 6 CLABSI events) per month (144 events per LTCH annually). This equates to a total of approximately 63,360 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical time (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN database. Based on this estimate, we expect each LTCH will expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN.

Therefore, the total estimated annual hourly burden on all LTCHs in the United States for reporting to NHSN is 26,400 hours. The estimated cost per submission is estimated at $12.07. These costs are estimated using an hourly wage for a registered nurse of $41.59 and a medical billing clerk/data entry person of $20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH will be $1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN will be $765,019.[184] While these requirements are subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently approved under OMB control number 0920–0666.

We estimate that each LTCH will execute only one NHSN submission per year (total number of vaccinations) as required by the CDC for the NHSN-reported Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431). This equates to a total of approximately 440 submissions of vaccination data to NHSN from all LTCHs per year. We estimate that each NHSN submission will take approximately 15 minutes to complete. This time estimate consists of 15 minutes of clerical time necessary to enter the data into the NHSN database. Based on this estimate, we expect each LTCH will expend 15 minutes per year reporting to NHSN. Therefore, the total estimated annual burden on all LTCHs in the United States for reporting this measure to NHSN is 110 hours. The estimated cost per submission is estimated at $3.90. The cost is estimated using an hourly wage for a medical billing clerk/data entry person of $15.59 (U.S. Bureau of Labor and Statistics data). We estimate the annual cost per each LTCH will be $3.90 and the total yearly cost to all LTCHs for the submission of the Influenza Coverage Among Healthcare Personnel measure (NQF #0431) will be $1,715.

Similar to the submission of CAUTI and CLABSI data, we estimate that each LTCH will execute approximately 12 NHSN submissions (6 MRSA events and 6 *C. Difficile* events) per month (144 events per LTCH annually). This equates to a total of approximately 63,648 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical time (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN. Based on this estimate, we expect each LTCH will expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN.

Therefore, the total estimated annual hourly burden on all LTCHs in the United States for reporting to NHSN is 26,400 hours. The estimated cost per submission is estimated at $12.07. These costs are estimated using an hourly wage for a registered nurse of $41.59 and a medical billing clerk/data entry person of $20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH will be $1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN will be $765,019.[185]

We estimate that the total annual cost to all LTCHs for submission of NHSN data will be $1,531,753 or $3,481 per LTCH annually.

We are proposing to adopt the updated measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the FY 2015 payment determination and subsequent payment determinations. This change would not alter the data collection, data submission, or burden finalized in the FY 2013 IPPS/LTCH PPS final rule and PRA package for LTCH CARE Data Set (Version 1.01)[186] since there have been no changes to the data elements, data submission system (QIES ASAP) and technical submission specifications for the LTCH CARE Data Set used for this measure for CY 2013 and first quarter of CY 2014. The only difference between the previously finalized measure and the proposed measure is the change in name and NQF-endorsed expansion of this measure to the LTCH (and IRF) patient populations in addition to Skilled Nursing Facility/Nursing Home Short-Stay residents. Therefore, the burden on providers for reporting of

[184] Nursing Time—24 hours @ $41.59 per hour = $998.16; $998.16 × 440 LTCHs = approximately $439,140; Administrative Time—36 hours @ $20.57 per hour = $740.52; $740.52 × 440 LTCHs = approximately $325,829; TOTAL = $439,140 + $325,829 = $765,019.

[185] Nursing Time—24 hours @ $41.59 per hour = $998.16; $998.16 × 440 LTCHs = approximately $439,140; Administrative Time—36 hours @ $20.57 per hour = $740.52; $740.52 × 440 LTCHs = approximately $325,829; TOTAL = $439,140 + $325,829 = $765,019.

[186] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html.*

data for NQF #0678 remains unchanged.[187]

In order to allow time and opportunity for LTCHs and vendors to participate in CMS-sponsored training activities pertaining to the implementation of the LTCH CARE Data Set (Version 2.01), as well as time to plan for and incorporate changes into their data collection and entry systems, we are proposing to revise the previously finalized start date for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) of January 1, 2014 to April 1, 2014. For CY 2014, data collection will continue through December 31, 2014. We are proposing that data for admissions and discharges for an LTCH during April 1, 2014 through December 31, 2014 will be used for the FY 2016 payment determination. Three items will be included on the LTCH CARE Data Set Version 2.01 for this measure. We have also removed several items from the administrative, functional status, and skin conditions sections of the LTCH CARE Data Set Version 1.01 to create the LTCH CARE Data Set Version 2.01,[188] so we anticipate that increase in burden due to the addition of items for NQF #0680 will be minimal. Later in 2013, we will release the final data submission specifications and updated LTCHQR Program Manual for the LTCH CARE Data Set (Version 2.01) containing items related to NQF #0680.

As previously mentioned, there are currently approximately 440 LTCHs in the United States paid under the LTCH PPS. We estimate that the total number of LTCH discharges per year is 202,050 [189] (134,700 Medicare beneficiaries and 67,350 non-Medicare beneficiaries). Therefore, the total number of discharges estimated for each LTCH is 457 annually and 38 monthly. We estimate that the total number of LTCH CARE Data Sets (LCDS) submitted by all LTCHs per year is 404,100 which equates to a total of 914 total LCDS submissions for each LTCH on an annual basis. The average number of LCDS submitted by each LTCH on a monthly basis is 76.

We estimate that the total time required to complete an LCDS per patient to be approximately 32 minutes,[190] which includes 11 minutes for the admission assessment, 11 minutes for the discharge assessment and 10 minutes for data entry. Therefore, each LTCH will spend approximately 1,216 minutes per month, or approximately 20.27 hours per month submitting the LCDS. We expect each LTCH to spend approximately 243 hours per year engaged in data collection and submission of the LCDS. Therefore, the total estimated burden to all LTCHs for reporting the LCDS is 106,920 hours per year.[191]

We estimate that the total annual cost to each LTCH will be approximately $6,751 to submit the LCDS. That estimate is based on the hourly wage for a registered nurse to complete the LCDS at $33.23 per hour and for an administrative assistant to transmit the LCDS at $15.59.[192] As previously stated, we estimate a total of 457 annual discharges (914 LCDS submissions) for each LTCH on an annual basis and that it will take 22 minutes total (11 minutes each) to complete the admissions and discharge assessments per patient. That is, 10,054 minutes of time, or 167.57 hours, that a registered nurse in each LTCH will spend completing the LCDS annually. For a registered nurse to spend 167.57 hours per year completing the LCSDs at a rate of $33.23 per hour, the associated cost for each LTCH will be approximately $5,568 and, for approximately 440 LTCHs, a total of $2,449,920 nursing wages per year.

Similarly, we previously estimated that it will take approximately 10 minutes per patient for data entry by an administrative assistant, resulting in approximately 4,570 minutes that each LTCH will spend transmitting the LCDS per year, or 76 administrative hours per year. At a rate of $15.59, that equates to approximately $1,185 for each LTCH and $521,330 for all LTCHs per year. Therefore, we estimate that the total annualized cost to each LTCH will be approximately $6,751 and $2,971,250 to all LTCHs.

While these requirements are subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently under consideration for approval under OMB control number 0920–0666.

We also are proposing the All-Cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals which we do not believe would increase LTCH provider burden because it is a Medicare FFS claims-based measure and does not require reporting of data other than submission of Medicare FFS claims data (LTCHs submit these data to CMS for payment purposes).

In section IX.C.8.c. of the preamble of this proposed rule, we are proposing one additional quality measure for use in the LTCHQR Program for the FY 2018 payment determination and subsequent payment determinations. We are proposing that LTCHs report data for an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure beginning January 1, 2016. It is our intent to foster alignment between measures by expanding preexisting data collection and submission methods to reduce the administrative burden related to data collection and submission. This measure will be collected using the LTCH CARE Data Set. The items used for the proposed application of the NQF #0674 will be based on the items from the Minimum Data Set (MDS) 3.0, version 1.13.0 (1/17/13) items J1800 (Any Falls Since Admission/Entry or Reentry or Prior Assessment) and J1900A, B and C (Number of Falls (A: with no injury, B: with injury (except major), C with Major injury)) since Admission/Entry or Reentry or Prior Assessment), available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html*. The calculation of the proposed application of the measure will be based on item J1900C, Number of Falls with major injury, since admission/entry or reentry or prior assessment. The specifications and data elements for NQF #0674 are available in the MDS 3.0 Quality Measures User's Manual Version 6.0 available on our Web site at: *http://www.cms.gov/*

[187] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*.

[188] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*.

[189] MedPAC Report to Congress, March 2012, page 261. Available at: *http://www.medpac.gov/documents/Mar12_EntireReport.pdf*.

[190] This time estimate includes the time required to complete both the required and voluntary questions on the LTCH CARE Data Set.

[191] 32 minutes/form × 38 forms per LTCH per month = 1,216 minutes per LTCH per month; 1,216 minutes/60 minutes per hour = 20.27 hours per LTCH per month; 20.27 hours per LTCH per month × 12 months/year = 243 hours per each LTCH/year; 243 hours/each LTCH per year × 440 LTCHs in U.S. = 106,920 hrs/all LTCHs/year.

[192] The mean hourly wage of $15.59 per hour for a Medical Secretary was obtained from the U.S. Bureau of Labor Statistics. We refer readers to: *http://www.bls.gov/oes/current/oes436013.htm*.

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.

We believe that the initial registration for use of the LTCH CARE Data Set, along with any necessary training, occurred for most LTCHs prior to the reporting of the Pressure Ulcer measure which began on October 1, 2012. Therefore, we believe the burden will be minimal related to the addition of this proposed quality measure into the LTCH CARE Data Set.

Therefore, we do not expect the addition of the NQF #0674 Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) measure to increase the burden substantially. Further, LTCHs will have been reporting data for the LTCHQR Program using the LTCH CARE Data Set for more than 2 years by the time the data collection begins for this measure.

At this time, we have not completed the revision of the information collection instrument (LTCH CARE Data Set) that LTCHs would be required to submit to report the proposed measure (NQF #0674) for the FY 2018 payment determination and subsequent payment determinations. Because the forms are still under development, we cannot make a complete burden estimate at this time for the inclusion of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) measure in the LTCH CARE Data Set. Once the forms are available, we will prepare and submit the required information collection request, which will fully set forth the anticipated burden to LTCHs as a result of the new data items that need to be added to the LTCH CARE Data Set.

10. ICRs for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of the FY 2013 IPPS/LTCH PPS final rule, we discussed the implementation of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program pursuant to the Secretary's authority under section 1886(s)(4) of the Act. We previously adopted six measures for the FY 2014 IPFQR Program payment determination and subsequent years. In section IX.D. of the preamble of this proposed rule, we are proposing that, for the FY 2016 payment determination and subsequent years, IPFs must submit aggregate data on three additional measures, for a total of nine measures. In addition, we are proposing a request for voluntary information.

To reduce the burden on IPFs, we are not proposing to make changes to the administrative, reporting or submission requirements for the existing six measures previously finalized in last year's rule (77 FR 53654 through 53657). However, there will be new reporting and submission requirements associated with the three proposed additional measures and the proposed request for voluntary information for the FY 2016 payment determination and subsequent years.

We believe that the proposed measures will help improve the quality of care provided by IPFs as we work to make quality data more transparent to the public. As required by the Act, we will share the information collected under the IPFQR Program with the public. These data will be displayed on the CMS Web site.

We have estimated the burden associated with IPFs complying with the requirements of the IPFQR Program. In our burden estimate calculation, we have included the time that would be spent for: (1) The submission of voluntary information; (2) chart abstraction; and (3) training personnel on the collection of chart-abstracted data, aggregation of the data, and for protocols to submit the aggregate-level data through QualityNet. We estimate that the annual hourly burden on each IPF for the collection, submission, and training of personnel for submitting all quality measures, including 30 minutes needed for the voluntary submission, is approximately 1,030 hours in a year for each IPF. Therefore, the average hourly burden on each IPF is approximately 86 hours per month. At this time, we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the aggregate impact.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1599–P; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*

C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as follows:

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), and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332).

■ 2. Section 412.3 is added to read as follows:

§ 412.3 Admissions.

(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with paragraph (b) of this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital.

(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is responsible for the inpatient care of the patient at the hospital. The practitioner may not delegate the decision (order) to another individual who is not responsible for the care of that patient, is not authorized by the State to admit patients, or has not been granted

admitting privileges applicable to that patient by the hospital's medical staff.

(c) Except as specified in paragraph (c)(2) of this section—

(1) When a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n) of this chapter, a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed. Surgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights. The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

(2) If an unforeseen circumstance, such as a beneficiary's death or transfer, result in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and hospital inpatient payment may be made under Medicare Part A.

■ 3. Section 412.46 is revised to read as follows:

§ 412.46 Medical review requirements.

(a) *Physician acknowledgement.* (1) *Basis.* Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement to this effect.

(2) *Content of physician acknowledgement statement.* When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice: Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(3) *Completion of acknowledgement.* The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

(b) *Physician's order and certification regarding medical necessity.* No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under subpart B of part 424 of the chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order or certification will be evaluated in the context of the evidence in the medical record.

■ 4. Section 412.64 is amended—

■ a. By adding paragraph (d)(1)(v).

■ b. In paragraph (h)(4) introductory text, by removing the date ''October 1, 2013'' and adding in its place the date ''October 1, 2014''.

■ c. In paragraph (h)(4)(vi), by removing the date ''October 1, 2013'' and adding in its place the date ''October 1, 2014''.

The addition reads as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(v) For fiscal year 2014, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.3 percentage point for prospective payment hospitals (as defined in § 413.40(a) of this chapter) for hospitals in all areas.

* * * * *

§ 412.101 [Amended]

■ 5. Section 412.101 is amended—

■ a. In paragraph (b)(2)(i), by removing the term ''FY 2013'' and adding in its place the term ''FY 2014.''

■ b. In paragraph (b)(2)(ii), by removing the phrase ''For FY 2011 and FY 2012,'' and adding in its place the phrase ''For FY 2011, FY 2012, and FY 2013,''.

■ c. In paragraph (c)(1), by removing the term ''FY 2013'' and adding in its place the term ''FY 2014.''

■ d. In paragraph (c)(2) introductory text, by removing the phrase ''For FY 2011 and FY 2012,'' and adding in its place the phrase ''For FY 2011, FY 2012, and FY 2013,''.

■ e. In paragraph (d), by removing the term ''FY 2013'' and adding in its place the term ''FY 2014.''

■ 6. Section 412.106 is amended by adding paragraphs (f), (g), and (h) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(f) *Empirically justified Medicare DSH payments.* Effective for discharges on or after October 1, 2013, the amounts otherwise payable to a hospital under paragraph (d) of this section are reduced by 75 percent.

(g) *Additional payment for uncompensated care.* (1) *Payment rules.* Hospitals that qualify for payments under this section for fiscal year 2014 and each subsequent year, will receive an additional amount equal to the product of the following three factors:

(i) *Factor 1.* For FY 2014 and each subsequent fiscal year, a factor equal to the difference between:

(A) The most recently available estimates, as calculated by CMS' Office of the Actuary, of the aggregate amount of payments that would be made to such hospitals under paragraphs (a) through (e) of this section if paragraph (f) of this section did not apply for the fiscal year; and

(B) The most recently available estimates, as calculated by CMS' Office of the Actuary, of the aggregate amount of payments that are made to such hospitals pursuant to paragraph (f) of this section for the fiscal year.

(ii) *Factor 2.* For each of fiscal years 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 (and subtracting from the factor 0.1 percentage point for fiscal year 2014 and 0.2 percentage point for each of fiscal years 2015, 2016, and 2017), as determined by comparing:

(A) 18 percent, the percent of such individuals who are uninsured in 2013, based on the March 20, 2010 estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office; and

(B) The percent of such individuals who are uninsured in the applicable fiscal year, based on the most recent estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office available at the time of development of the annual final rule for the hospital inpatient prospective payment system.

(iii) *Factor 3.* A factor equal to the percent, for each inpatient prospective payment system hospital, that represents the quotient of:

(A) The amount of uncompensated care for such hospital as estimated by CMS.

(B) The aggregate amount of uncompensated care as estimated by CMS for all hospitals that are estimated to receive a payment under this section.

(C) Beginning with fiscal year 2014, 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.

(iv) The final values for each of the three factors are determined for each fiscal year at the time of development of the annual final rule for the hospital inpatient prospective payment system, and these values are used for both interim and final payment determinations.

(2) *Preclusion of administrative and judicial review.* There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

(i) Any estimate of the Secretary for the purpose of determining the factors in section paragraph (g)(1) of this section; and

(ii) Any period selected by the Secretary for such purposes.

(h) *Manner and timing of payments.* (1) Interim payments are made on a periodic basis during the payment year to each hospital that is estimated to be eligible for payments under this section at the time of the annual final rule for the hospital inpatient prospective payment system, subject to the final determination of eligibility at the time of cost report settlement for each hospital.

(2) Final payment determinations are made at the time of cost report settlement, based on the final determination of each hospital's eligibility for payment under this section.

§ 412.108 [Amended]

■ 7. Section 412.108 is amended—

■ a. In paragraph (a)(1) introductory text, by removing the phrase ''before October 1, 2012'' and adding in its place the phrase ''before October 1, 2013''.

■ b. In paragraph (c)(2)(iii) introductory text, by removing the phrase ''before October 1, 2012'' and adding in its place the phrase ''before October 1, 2013''.

■ 8. Section 412.140 is amended by revising the section heading and paragraphs (a)(3) introductory text and (b) and adding paragraph (f) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

(a) * * *

(3) Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CCN).

* * * * *

(b) *Withdrawal from the Hospital IQR Program.* CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before—

(1) Prior to the FY 2016 payment determination, August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR determination will be made.

(2) Beginning with the FY 2016 payment determination, May 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

* * * * *

(f) *Patient experience of care data (HCAHPS survey).* HCAHPS is the Hospital Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent hospital stay.

(1) Approved HCAHPS survey vendors and self-administering hospitals must fully comply with all HCAHPS oversight activities, including allowing CMS and its HCAHPS Project Team to perform site visits at the hospitals' and survey vendors' company locations.

(2) CMS approves an application for an entity to administer the HCAHPS survey as an approved HCAHPS survey vendor on behalf of one or more hospitals when an applicant has met the Minimum Survey Requirements and Rules of Participation listed in the most recently available version of the HCAHPS *Quality Assurance Guidelines,* available on the official HCAHPS On-Line Web site, and agree to comply with the survey administration protocols contained in the most recently available version of the HCAHPS *Quality Assurance Guidelines* and as updated through HCAHPS Bulletins and announcements on the official HCAHPS On-Line Web site. An entity must be an approved HCAHPS survey vendor in order to administer and submit HCAHPS data to CMS on behalf of one or more hospitals.

■ 9. Section 412.150 is amended by adding paragraph (c) to read as follows:

§ 412.150 Basis and scope of subpart.

* * * * *

(c) Section 1886(p) of the Act requires the Secretary to establish an adjustment to hospital payments for hospital-acquired conditions, or a Hospital-Acquired Condition Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions, effective for discharges beginning on October 1, 2014. The rules for determining the payment adjustment under the Hospital-Acquired Condition Reduction Program are specified in §§ 412.170 and 412.172.

■ 10. Section 412.152 is amended by revising the definition of ''Base operating DRG payment amount'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101. With respect to a sole community hospital that receives payments under § 412.92(d) or a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) for FY 2013, this amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part. With respect to a hospital that is paid under section 1814(b)(3) of the Act, this amount is an amount equal to the wage adjusted DRG payment amount plus new technology payments that would be paid to such hospitals, absent the provisions of section 1814(b)(3) of the Act.

* * * * *

■ 11. Section 412.154 is amended by revising paragraph (d)(2) to read as follows:

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(d) * * *

(2)(i) Maryland's annual report to the Secretary and request for exemption

from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually.

(ii) Beginning with the FY 2015 program year—

(A) The State must submit a preliminary report to CMS no later than January 15 of each year for the Secretary to consider, through the annual proposed rule, its exemption from the Hospital Readmissions Reduction Program for the upcoming Federal fiscal year.

(B) The State must submit a final report to CMS no later than June 1 of each year for the Secretary to consider, through the annual final rule, its exemption from the Hospital Readmissions Reduction Program in the upcoming Federal fiscal year.

(C) The reports required under paragraphs (d)(2)(ii)(A) and (B) of this section must include information as specified by CMS.

* * * * *

■ 12. Section 412.160 is amended by revising the definitions of ''Achievement threshold'' and ''Benchmark'' to read as follows:

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.

* * * * *

Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.

* * * * *

■ 13. An undesignated center heading and §§ 412.170 and 412.172 are added to subpart I to read as follows:

Payment Adjustments under the Hospital-Acquired Condition Reduction Program

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

As used in this section and § 412.172, the following definitions apply:

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act (including a hospital in Maryland that is paid under the waiver under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the hospital inpatient prospective payment system) as long as the hospital meets the criteria specified under § 412.172(e).

Applicable period is, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

Hospital-acquired condition is a condition as described in section 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.

§ 412.172 Payment adjustments under the Hospital-Acquired Condition Reduction Program.

(a) *Scope.* This section sets forth the requirements for determining the payment adjustments under the Hospital-Acquired Condition Reduction Program for hospitals that meet the criteria described under paragraph (e) of this section.

(b) *Payment adjustment.* With respect to all discharges from an applicable hospital occurring during FY 2015 or a subsequent year, the amount of payment under this section, or section 1814(b)(3) of the Act as applicable, for such discharges during the fiscal year will be equal to 99 percent of the amount of payment that would otherwise apply to these discharges under this section or section 1814(b)(3) of the Act (determined after the application of the payment adjustment under the Hospital Readmissions Reduction Program under § 412.154 and the adjustment made under the Hospital Value-Based Purchasing Program under § 412.162 and section 1814(l)(4) of the Act but without regard to section 1886(p) of the Act).

(c) *Hospitals paid under section 1814(b)(3) of the Act (certain Maryland hospitals).* CMS will determine whether to exempt Maryland hospitals that are paid under section 1814(b)(3) of the Act and not under the hospital inpatient prospective payment system from the application of the payment adjustments under this section. The State must submit an annual report to CMS that describes how a similar program to reduce hospital-acquired conditions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings for the Hospital-Acquired Conditions Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act.

(1) CMS will establish criteria for evaluation of Maryland's annual report to determine whether the State will be exempted from the application of the payment adjustments under this section for a given fiscal year.

(2) Maryland's annual report and request for exemption from the Hospital-Acquired Condition Reduction Program must be resubmitted and reconsidered annually.

(d) *Risk adjustment.* In carrying out the provisions of paragraph (e) of this section, CMS will establish and apply an appropriate risk-adjustment methodology.

(e) *Criteria for applicable hospitals.* (1) *General.* With respect to a subsection (d) hospital, CMS will identify the top quartile of all subsection (d) hospitals with respect to hospital-acquired conditions as measured during the applicable period.

(2) *Use of total hospital-acquired condition scores.* CMS will use total hospital-acquired condition scores to identify applicable hospitals. CMs will identify the 25 percent of hospitals with the highest total scores.

(3) *Methodology for calculating total hospital-acquired condition scores.* CMS will calculate the total hospital-acquired condition scores by weighing the selected measures according to the established methodology.

(f) *Reporting of hospital-specific information.* CMS will make information available to the public regarding hospital-acquired condition rates of all hospitals under the Hospital-Acquired Reduction Program.

(1) CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its total hospital-acquired condition score.

(2) Hospitals will have a period of 30 days after the receipt of the information provided under paragraph (f)(1) of this section to review and submit corrections for the hospital-acquired condition domain score for each condition that is used to calculate the score for the fiscal year.

(3) The administrative claims data used to calculate a hospital's total hospital-acquired condition score for the condition for a fiscal year are not subject to review and correction under paragraph (f)(2) of this section.

(4) CMS will post the total hospital-acquired condition score for the applicable conditions for a fiscal year for each hospital on an appropriate Web site.

(g) *Limitations on review.* There is no administrative or judicial review under § 412.170 and this section for the following:

(1) The criteria describing applicable hospitals.

(2) The applicable period.

(3) The specification of hospital-acquired conditions.

(4) The provision of reports to hospitals and the information made available to the public.

■ 14. Section 412.523 is amended by—

■ a. Revising paragraph (c)(3) introductory text.

■ b. Adding paragraph (c)(3)(x).

■ c. Redesignating paragraph (c)(4) as paragraph (c)(5).

■ d. Adding a new paragraph (c)(4).

The additions read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) *Computation of the standard Federal rate.* Subject to the provisions of paragraph (c)(4) of this section, the standard Federal rate is computed as follows:

* * * * *

(x) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2013, and ending September 30, 2014.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2013, and ending September 30, 2014, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(4) *For fiscal year 2014 and subsequent fiscal years*—(i) In the case of a long-term care hospital that does not submit quality reporting data to CMS in the form and manner and at a time specified by the Secretary, the annual update to the standard Federal rate specified in paragraph (c)(3) of this section is further reduced by 2.0 percentage points.

(ii) Any reduction of the annual update to the standard Federal rate under paragraph (c)(4)(i) of this section will apply only to the fiscal year involved and will not be taken into account in computing the annual update to the standard Federal rate for a subsequent fiscal year.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 15. The authority citation for Part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 16. Section 482.23 is amended by revising paragraph (c)(3) introductory text to read as follows:

§ 482.23 Condition of participation: Nursing services.

* * * * *

(c) * * *

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 17. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 18. Section 485.620 is amended by revising paragraph (a) to read as follows:

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.

* * * * *

■ 19. Section 485.635 is amended by revising paragraphs (a)(3)(vii), (b)(1), and (c)(1) to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(3) * * *

(vii) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving posthospital SNF care.

* * * * *

(b) * * *

(1) *General:* (i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(ii) The CAH furnishes acute care inpatient services.

* * * * *

(c) * * *

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Services of doctors of medicine or osteopathy;

(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 20. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102 1819, 1820(E), 1861, 1864(M), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh)).

■ 21. In § 489.24, the paragraph (f) heading is revised to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

(f) *Recipient hospital responsibilities.* * * *

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance)

Dated: April 24, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 25, 2013.

Kathleen Sebelius,

Secretary.

Note: The following addendum and appendices will not appear in the Code of Federal Regulations.

Addendum—Proposed Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2013 and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2013

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2014 for acute care hospitals. We also are setting forth the proposed rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS for FY 2014. 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 proposed rule, we are proposing the rate-of-increase percentages 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, 2013.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that would be applicable to Medicare LTCHs for FY 2014.

In general, except for SCHs and hospitals located in Puerto Rico, for FY 2014, 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.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

We note that section 606 of the American Taxpayer Relief Act of 2012 (ATRA) extended the MDH program from the end of FY 2012 (that is, for discharges occurring before October 1, 2012) to the end of FY 2013 (that is, for discharges occurring before October 1, 2013). Under prior law, the MDH program was to be in effect through the end of FY 2012 only. Absent additional legislation further extending the MDH program, the MDH program will expire for discharges beginning in FY 2014. Therefore, due to the expiration of the MDH program beginning with FY 2014, we are not including hospitals that are currently MDHs (until October 1, 2013) in our update of the hospital-specific rates for FY 2014.

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.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2014. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2014. In section IV. of this Addendum, we are setting forth our proposed changes for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2014. In section V. of this Addendum, we are proposing to make changes in the determination of the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2014. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the Internet.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2014

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we are using for determining the proposed prospective payment rates for FY 2014.

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) 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.
- A proposed update of 1.8 percent for all areas (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for MFP and less 0.3 percentage point), as required by section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. For hospitals that fail to submit data, in a form and manner, and at the time, specified by the Secretary relating to the quality of inpatient care furnished by the hospital, pursuant to section 1886(b)(3)(B)(viii) of the Act, the proposed update is –0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.4 percentage point for MFP, and less 0.3 percentage point).
- A proposed update of 1.8 percent to the Puerto Rico-specific standardized amount (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for MFP and less 0.3 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 2013 budget neutrality factor and applying a revised factor.
- 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 2013 outlier offset and apply an offset for FY 2014, 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 proposed rule, a proposed recoupment to meet the requirements of section 631 of 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.
- As discussed below and in section V.N. of the preamble of this proposed rule, a proposed adjustment to offset the cost of the policy proposal on admission and medical

review criteria for hospital inpatient services under Medicare Part A.

Beginning in FY 2008, we applied the budget neutrality adjustment for the rural floor to the hospital wage indices rather than the standardized amount. As we did for FY 2013, for FY 2014, consistent with current law, we are proposing to continue to apply the rural floor budget neutrality adjustment to hospital wage indices rather than the standardized amount. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the proposed FY 2014 wage index for the rural floor. We note that, in section III.G.2.b. of the preamble to this proposed rule, we are proposing to extend the imputed floor policy (both the original methodology and alternative methodology) for one additional year, through September 30, 2014.

Therefore, for this proposed rule, we are proposing to continue to include the imputed floor (calculated under the original and alternative methodologies) in calculating the uniform, national rural floor budget neutrality adjustment, which will be reflected in the proposed FY 2014 wage index.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. 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.

In accordance with section 1886(d)(3)(E) of the Act, the Secretary estimates, from time-to-time, the proportion of hospitals' costs that are attributable to wages and wage-related costs. In general, the standardized amount is divided into labor-related and nonlabor-related amounts; only the proportion considered to be the labor-related amount is adjusted by the wage index. Section 1886(d)(3)(E) of the Act requires that 62 percent of the standardized amount be adjusted by the wage index, unless doing so would result in lower payments to a hospital than would otherwise be made. (Section 1886(d)(9)(C)(iv)(II) of the Act extends this provision to the labor-related share for hospitals located in Puerto Rico.)

For FY 2014, we are proposing to rebase and revise the national and Puerto Rico-specific labor-related and nonlabor-related shares from the percentages established for FY 2013. 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: ''The Secretary shall 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 proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2014, as discussed in section IV.B.4. of the preamble of this proposed rule, we are proposing a labor-related share of 69.6 percent for the national standardized amounts and 63.2 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E) of the Act, we are the wage index to a labor-related share of 62 percent for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indices are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 69.6 percent of the national standardized amount. For FY 2014, all Puerto Rico hospitals have a proposed wage index less than 1.0 because the proposed average hourly rate of every hospital in Puerto Rico divided by the proposed 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 proposed wage index below 1.0000. Therefore, the national labor-related share would be 62 percent because the proposed wage index for all Puerto Rico hospitals is less than 1.0.

When we divide the proposed average hourly rate of every hospital in Puerto Rico by the proposed Puerto Rico-Specific national average hourly rate (the sum of all salaries and hours for all hospitals only in Puerto Rico), we determine a proposed Puerto Rico Specific wage index above or below 1.0000, depending on the hospital. For hospitals located in Puerto Rico, we are proposing to apply 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 proposing to apply a labor share of 62 percent.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet.

2. Computing the Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are proposing to calculate the proposed FY 2014 national standardized amount and Puerto Rico-specific rate irrespective of whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace 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. As discussed in section V.A. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the proposed FY 2014 applicable percentage increase (which is based on the first quarter 2013 forecast of the FY 2010-based IPPS market basket) by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending FY 2014) of 0.4 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) first quarter 2013 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2014 by the estimated market basket percentage increase less 0.3 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of 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 2013 first quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the most recent forecast of the hospital market basket increase for FY 2014 is 2.5 percent. Thus, for FY 2014, the proposed update to the average standardized amount is 1.8 percent for hospitals in all areas (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for MFP and less 0.3 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii) of the Act, the estimated update to the proposed operating

standardized amount is −0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less a proposed adjustment of 0.4 percentage point for MFP, and less 0.3 percentage point). The proposed standardized amounts in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet 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 proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.8 percent.

Although the update factors for FY 2014 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 2014 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 proposed rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are proposing to adjust the FY 2014 standardized amount to remove the effects of the FY 2013 geographic reclassifications and outlier payments before applying the proposed FY 2014 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2014 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.

First, 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.

Second, 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).

Third, 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 health care organizations selected to participate in the BPCI initiative. 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 rate setting 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). Therefore, for FY 2014, 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 the reader to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals in the BPCI initiative in our rate setting process.

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 proposed rule, consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe 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 V.G. of the preamble of this proposed rule for full details of our implementation of 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 that meet performance standards 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 V.H. of the preamble of this proposed rule for full 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.4.a. of this Addendum for full 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, for FY 2014 and subsequent years, we are proposing to continue to apply the hospital readmissions payment adjustment and the hospital VBP payment adjustment on each side of the comparison consistent with the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply 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 proposed FY 2014 readmissions payment adjustment factors, we are proposing to use 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. The data from the proposed applicable period for FY 2014 have not yet been through the review and correction process required by section 1886(q)(6) of the Act. For the final rule, we intend to calculate 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 2014 as hospitals will have had the opportunity to review and correct these data before the data are made public under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our proposed policy regarding the reporting of hospital-specific readmission rates for FY 2014 in section V.G.3.f. of the preamble of this proposed 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 this proposed rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proposed hospital VBP payment adjustment factors for FY 2014 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 2014 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 establishes a new section 1886(r) of the Act that modified the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving DSH adjustments will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. 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, 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 FY2014, 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 2014 and subsequent years, we are proposing to include estimated DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and also to include estimates of the additional payments made to hospitals receiving Medicare DSH as described by section 1886(r)(2) of the Act. That is, we are proposing to include estimated Medicare DSH payments at 25 percent of what would otherwise be paid and also the estimated additional payments for hospitals receiving Medicare DSH on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

a. Proposed 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 proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

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 1.0, 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 indices less than or equal to 1.0 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 1.0 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2014, we are proposing to adjust 100 percent of the wage index factor for

occupational mix. We describe the occupational mix adjustment in section III.F. of the preamble of this proposed rule.

For FY 2014, 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 2012 discharge data to simulate payments and compared aggregate payments using the FY 2013 labor-related share percentages, the FY 2013 relative weights, and the FY 2013 pre-reclassified wage data and applied the proposed FY 2014 hospital readmissions payment adjustments and estimated FY 2014 hospital VBP payment adjustments to aggregate payments using the FY 2013 labor-related share percentages, the proposed FY 2014 relative weights, and the FY 2013 pre-reclassified wage data and applied the same hospital readmissions payment adjustments and estimated hospital VBP payment adjustments. Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.997583. As discussed in section IV. of this Addendum, we also are proposing to apply the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.997583 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2013.

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, 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. We first determined a proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.997583 (by using the same methodology described above to determine the proposed MS–DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates). Secondly, to compute a proposed budget neutrality factor for wage index and labor-related share changes, we used FY 2012 discharge data to simulate payments and compared aggregate payments using the proposed FY 2014 relative weights and the FY 2013 pre-reclassified wage indices, applied the FY 2013 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the proposed FY 2014 hospital readmissions payment adjustment and the FY 2014 estimated hospital VBP payment adjustment when estimating aggregate payments using the proposed FY 2014 relative weights and the proposed FY 2014 pre-reclassified wage indices, applied the proposed labor-related share for FY 2014 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0), and applied the same proposed FY 2014 hospital readmissions payment adjustments and estimated FY 2014 hospital VBP payment adjustments. In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the rates that were used to simulate payments for this comparison of aggregate payments from FY 2013 to FY 2014. By applying this methodology, we determined a proposed budget neutrality factor of 0.999766 for changes to the wage index. Finally, we multiplied the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.997583 (derived in the first step) by the proposed budget neutrality factor of 0.999766 for changes to the wage index (derived in the second step) to determine the proposed MS–DRG reclassification and recalibration and updated wage index budget neutrality factor of 0.99735.

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 proposed budget neutrality factor for FY 2014, we used FY 2012 discharge data to simulate payments and compared total IPPS payments with proposed FY 2014 relative weights, proposed FY 2014 labor-related share percentages, and proposed FY 2014 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act and applied the proposed FY 2014 hospital readmissions payment adjustments and the estimated FY 2014 hospital VBP payment adjustments to total IPPS payments with proposed FY 2014 relative weights, proposed FY 2014 labor-related share percentages, and proposed FY 2014 wage data after such reclassifications and applied the same hospital readmissions payment adjustments and the estimated hospital VBP payment adjustments. Based on these simulations, we calculated a proposed adjustment factor of 0.990971 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2014 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2013 budget neutrality adjustment factor. We note that the proposed FY 2014 budget neutrality adjustment reflects proposed FY 2014 wage index reclassifications approved by the MGCRB or the Administrator.

c. Proposed Rural Floor Budget Neutrality Adjustment

As noted above, as discussed in section III.G.2.b. of the preamble of this proposed rule, in the FY 2012 IPPS/LTCH PPS final rule, we extended the imputed floor calculated under the original methodology through FY 2013 (76 FR 51594). In the FY 2013 IPPS/LTCH PPS final rule, 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 (77 FR 53368 through 53369). We make an adjustment to the wage index to ensure that aggregate payments to hospitals 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) of the regulations are not affected. In addition, we note in section III.G.2.b. of the preamble of this proposed rule, we are proposing to extend the imputed floor using the higher of the value determined under the original methodology or the alternative methodology for FY 2014. Consistent with the methodology for treating the imputed floor, similar to the methodology we used in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), 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. Also, consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of this proposed rule, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

Since FY 2012, there has been one hospital in rural Puerto Rico. Therefore, similar to our calculation in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593 and 51788) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53689), for FY 2014, we are proposing to calculate 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 this rural Puerto Rico hospital still has no established wage data, our calculation is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). A complete discussion regarding the computation of the rural Puerto Rico wage index can be found in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51594).

To calculate the proposed national rural floor and imputed floor budget neutrality adjustment factor and the proposed Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2012

discharge data and proposed FY 2014 post-reclassified national and Puerto Rico-specific wage indices to simulate IPPS payments. First, we compared the national and Puerto Rico-specific simulated payments without the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to the national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to determine the proposed national rural budget neutrality adjustment factor of 0.990189 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.990877. The national adjustment is applied to the national wage indices to produce a national rural floor budget neutral wage index and the Puerto Rico-specific adjustment is applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Proposed Case-Mix Budget Neutrality Adjustment

Below we summarize the proposed recoupment adjustment to the FY 2014 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 proposed rule for a complete discussion regarding our proposals 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. We note that section II.D. of the preamble of this proposed rule also includes a discussion on documentation and coding effects that occurred through FY 2010, including a request for public comments as to whether any portion of the proposed −0.8 percent recoupment adjustment discussed below should be reduced and instead applied as a prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010.

(1) 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 estimate that if CMS were to fully account for the $11 billion recoupment required by section 631 of 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 rate adjustments over more than one year, in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we are proposing a −0.8 percent adjustment to the standardized amount in FY 2014. We note that, as section 631 of the ATRA instructs CMS to make a recoupment adjustment only to the standardized amount, this proposed adjustment would not apply to the Puerto Rico-specific rate.

e. Proposed Adjustment To Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A

In the Medicare Part B Inpatient Billing in Hospitals proposed rule that went on display at the Office of the Federal Register on March 13, 2013, and that appeared in the **Federal Register** on March 18, 2013 (78 FR 16632), we proposed to revise our Part B inpatient billing policy to allow payment of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient, except for those services specifically requiring an outpatient status. This policy would apply when CMS or a Medicare review contractor determines that the hospital admission was not reasonable and necessary or when a hospital determines after a beneficiary has been discharged that the beneficiary should have received hospital outpatient services rather than hospital inpatient services. We also proposed to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service. As we discuss in section V.N. of the preamble to this proposed rule, in addition to evaluating our policy related to Part B inpatient billing following denials of Part A inpatient claims on the basis that the inpatient admission was not reasonable and necessary or following self-audit, we also believe it is important to consider whether we can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment. Toward that end, in section V.N.3. of the preamble of this proposed rule, we present a proposal that would clarify that a beneficiary becomes a hospital inpatient when formally admitted following the physician order for hospital inpatient admission, and would also clarify when we believe hospital inpatient admissions are reasonable and necessary based on how long beneficiaries have spent, or are reasonable expected to spend, in the hospital as inpatients. Under this proposal, Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than one Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services. Similarly, we would presume that generally services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required an inpatient level of care. (For a complete discussion on our proposed inpatient admission guidelines, including our proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for payment of hospital inpatient services under Medicare Part A, we refer readers to section V.N.3 of this proposed rule.)

Our actuaries project a net increase in IPPS expenditures as a result of the proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services, discussed in section V.N.3. of the preamble of this proposed rule (as summarized above). These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. In making this projection, the actuaries analyzed Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters, and estimated the number of encounters that are expected to shift from outpatient to inpatient and vice versa (that is, the number that are expected to shift from inpatient to outpatient). In section V.N.5. of the preamble of this proposed rule, we discuss that our actuaries estimate that this projected net increase in inpatient encounters would increase IPPS expenditures by approximately $220 million. In light of the widespread impact on the IPPS of the proposed policy and the systemic nature of the issue, we believe it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the estimated $220 million in additional IPPS expenditures associated with this proposed policy by proposing to reduce the national standardized amount, the Puerto Rico-specific standardized amount, and hospital-specific rates by 0.2 percent (or 0.998 adjustment). We refer readers to section V.N.4. of the preamble of this proposed rule for a complete discussion on this proposed adjustment to offset the estimated cost of the proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for hospital inpatient services under Medicare Part A.

f. Proposed Rural Community Hospital Demonstration Program Adjustment

As discussed in section V.K. of the preamble to this proposed 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 ''[i]n 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 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), in order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration program as described in section IV.K. 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 that 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 2014, for the 23 hospitals participating in the demonstration program, we are proposing to adjust the national IPPS payment rates according to the same methodology that we used for FY 2013, as set forth in section V.K. of the preamble of this proposed rule. For this proposed rule, the estimated amount for the proposed adjustment to the national IPPS payment rates for FY 2014 is $46,515,865. (The estimated amount for the adjustment to the national IPPS payment rates for FY 2013 was $34,288,129.) Accordingly, to account for the estimated costs of the demonstration program, for FY 2014, we computed a factor of 0.999834 for the rural community hospital demonstration program budget neutrality adjustment that would be applied to the IPPS standard Federal payment rate.

We note that if updated data became available prior to the publication of the FY 2014 IPPS/LTCH PPS final rule, we are proposing to use that data, to the extent appropriate, to estimate the costs of the demonstration program in FY 2014. Therefore, this estimated budget neutrality offset amount may change in the final rule to reflect the updated data.

In addition, if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009 or 2010) are made available prior to the FY 2014 IPPS/LTCH PPS final rule, we are proposing to incorporate into the FY 2014 budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration in any of these years (as described previously) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

g. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the 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 2014 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) Proposed FY 2014 Outlier Fixed-Loss Cost Threshold

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53691 through 53696), we received comments from the public concerning our methodology for calculating the outlier threshold. Specifically, many commenters expressed concern that CMS is still not reaching the 5.1 percent target for outlier payments and believed there is still room for improvement. The commenters made various suggestions to improve the current methodology used to calculate the outlier threshold. In that final rule we responded that we appreciate the commenters providing multiple alternative methodologies to adjust the CCRs used in our outlier fixed-loss cost threshold. Due to the many options the commenters presented, we stated that the most prudent approach was to study the merits of each methodology and, if appropriate, make a proposal in the FY 2014 IPPS/LTCH PPS proposed rule if we believe making a change to our current methodology would improve our methodology for projecting the outlier fixed-loss cost threshold. Since publication of the FY 2013 IPPS/LTCH PPS final rule, we have studied the merits of the commenters' suggestions to improve the outlier threshold methodology. Below we discuss our proposed outlier methodology for FY 2014 with revisions from the prior fiscal year.

As we have done in the past, to calculate the proposed FY 2014 outlier threshold, we simulated payments by applying proposed FY 2014 payment rates and policies using cases from the FY 2012 MedPAR file. Therefore, in order to determine the proposed FY 2014 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2012 to FY 2014. Since FY 2005, we have used the same methodology to inflate charges. For FY 2014 and subsequent years, we are proposing to further refine our current methodology which uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy. In the FY 2005 IPPS final rule (69 FR 49277), to compute the 1-year average annualized rate-of-change in charges per case, we stated that we were taking the unprecedented step of comparing the average charge per case from the most recent 6 month period of charge data available to the average charge per case from the same 6 month period from the prior year rather than using a full year of charge data. At that time, we noted that we adopted this methodology to calculate the outlier threshold for FY 2005 as a result of the special circumstances surrounding the revisions to the outlier payment methodology; specifically the exceptionally high rate of hospital charge inflation that was reflected in the data for FYs 2001, 2002, and 2003. We also noted that we would continue to consider other methodologies for determining charge inflation when calculating the outlier threshold in the future. We refer the reader to the FY 2005 IPPS final rule for a complete discussion on this methodology.

For FY 2014, if we were to propose to continue to use our current methodology that we adopted in FY 2005, we would have computed the 1-year average annualized rate-of-change in charges per case by comparing the last quarter of FY 2011 in combination with the first quarter of FY 2012 (July 1, 2011, through December 31, 2011) to the last quarter of FY 2012 in combination with the first quarter of FY 2013 (July 1, 2012, through December 31, 2012). This rate-of-change was 4.7 percent (1.046908) or 9.6 percent (1.096016) over 2 years. After nine years of using the same methodology, the special circumstances of the exceptionally high rate of hospital charge inflation that was reflected in the data for FYs 2001, 2002, and 2003 may not be as applicable. We believe the policies that we implemented in the FY 2003 Outlier final rule (outlier reconciliation and no longer assigning the statewide average CCR for those hospitals that fall below a CCR floor) have helped control inflation of hospital charges.

Therefore, instead of comparing periods of the most recent 6 months of charge data, we are proposing to adopt a new methodology to inflate charges that use periods of 1-year of the most recent charge data. 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 since a 6 month measure inherently uses fewer claims than a 1-year measure, which makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. Under this new proposed methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2014, we are proposing to compare the second quarter of FY 2011 through the first quarter of FY 2012 (January 1, 2011, through December 31, 2011) to the second quarter of FY 2012 through the first quarter of FY 2013 (January 1, 2012, through December 31, 2012). This rate-of-change was 4.8 percent (1.048458) or 9.9 percent (1.099264) over 2 years.

As we have done in the past, we are proposing to establish the proposed FY 2014 outlier threshold using hospital CCRs from the December 2012 update to the Provider-Specific File (PSF)—the most recent available data at the time of this proposed rule. For FY 2014, we are also proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). In the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to develop the current methodology used to adjust the CCRs. We have used this same methodology to adjust the CCRs from FY 2007 through FY 2013.

Over the years, many commenters have stated that our current methodology is unnecessary complicated. In addition, as mentioned above, in the FY 2013 IPPS/LTCH PPS final rule, commenters made various suggestions to improve the current methodology used to calculate the outlier threshold and we stated that we would study the merits of each methodology and, if appropriate, make a proposal in the FY 2014 IPPS/LTCH PPSproposed rule if we believe making a change to our current methodology would improve our projection of the outlier fixed-loss cost threshold. In that same final rule, some commenters suggested the use of historical CCR data from the PSF to compute a rate-of-change in CCRs. Under this approach, the commenters compared 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. The commenters stated that although this adjustment would be based on 1 year's data, the commenters believed that the use of historical data to adjust the CCRs is consistent with CMS' estimation of charge inflation. After reviewing the commenters' suggestion, we agree that the use of historical data to adjust the CCRs is simpler and is consistent with CMS' estimation of charge inflation.

Therefore, for FY 2014, we are proposing to adjust the CCRs from the December 2012 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2011 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2012 update of the PSF. We note that we used total transfer-adjusted cases from FY 2012 to determine the national average case-weighted CCRs for both sides of the comparison. We believe 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 proposed methodology above, we calculated a December 2011 operating national average case-weighted CCR of 0.303178 and a December 2012 operating national average case-weighted CCR of 0.295049. We then calculate the percentage change between the two national operating case-weighted CCRs by subtracting the December 2011 operating national average case-weighted CCR from the December 2012 operating national average case-weighted CCR and then dividing by the December 2011 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.973187.

We used the same methodology proposed above to also adjust the capital CCRs. Specifically, we calculated a December 2011 capital national average case-weighted CCR of 0.025994 and a December 2012 capital national average case-weighted CCR of 0.0249373. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2011 capital national average case-weighted CCR from the December 2012 capital national average case-weighted CCR and then dividing by the December 2011 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.959337.

Consistent with our methodology in the past and as stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a fiscal intermediary or 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 2009 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 2014, we applied the proposed FY 2014 rates and policies using cases from the FY 2012 MedPAR files in calculating the proposed outlier threshold.

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.G.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be 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 will receive a wage index lesser than 1.00 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 2014, it was necessary to apply this provision by adjusting 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 2014. If we did not take into account this provision, our estimate of total FY 2014 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 2014 outlier payments, we are not proposing to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also noted that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

As described in sections V.G. and V.H., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe 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 would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

Using this proposed methodology, we are proposing an outlier fixed-loss cost threshold for FY 2014 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $24,140.

We note that the proposed FY 2014 threshold is higher than the FY 2013 final outlier threshold of $21,821. We believe that the decrease in DSH payments due to the implementation of section 1886(r)(1) of the Act contributed to a higher proposed fixed-loss outlier threshold for FY 2014. We note that the additional payments based on uncompensated care made to hospitals receiving Medicare DSH under section 1886(r)(2) of the Act are not taken into consideration when determining outlier payments because we did not propose to make this payment on a per discharge basis. However, when computing a claim by claim outlier threshold, we calculate DSH payments under section 1886(d)(5)(f) of the Act with the reduction under section 1886(r)(1) (the original DSH amount multiplied by 0.25). Therefore, we believe that, decreasing DSH payments decreases total funds to typical cases, which is used to compute the claim by claim outlier threshold thus leading to an increase in outlier payments. This requires that we raise the outlier threshold to decrease the amount of outlier dollars expended in order to reach the 5.1 percent target.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2014 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.49 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2014 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the standardized amount based on the FY 2014 outlier threshold are as follows:

	Operating standardized amounts	Capital Federal rate
National	0.948997	0.945149
Puerto Rico ...	0.952600	0.944392

We are proposing to apply the outlier adjustment factors to the proposed FY 2014 rates after removing the effects of the FY 2013 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 fiscal intermediary or MAC computes operating CCRs greater than 1.152 or capital CCRs greater than 0.166, or hospitals for which the fiscal intermediary or 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) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the fiscal intermediary or MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2013, these statewide average ratios would replace the ratios posted on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2013-IPPS-Final-Rule-Home-Page-Items/FY2013-Final-Rule-Tables.html*. Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the proposed comparable statewide average capital CCRs. Again, the CCRs in Tables 8A and 8B would be used during FY 2014 when hospital-specific CCRs based on the latest settled cost report are either not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or 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 fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thus 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, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf*.

(3) FY 2012 and FY 2013 Outlier Payments

In the FY 2013 IPPS final rule (77 FR 53697 through 53698), we stated that, based on available data, we estimated that actual FY 2012 outlier payments would be approximately 5.0 percent of actual total MS–DRG payments. This estimate was computed based on simulations using the FY 2011 MedPAR file (discharge data for FY 2011 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2012 claims, but instead reflected the application of FY 2012 payment rates and policies to available FY 2011 claims.

Our current estimate, using available FY 2012 claims data, is that actual outlier payments for FY 2012 were approximately 5.47 percent of actual total MS–DRG payments. Thus, the data indicate that, for FY 2012, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2012. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not plan to make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2012 are equal to 5.1 percent of total MS–DRG payments.

We currently estimate that, using the latest CCRs from the March 2013 update of the PSF, actual outlier payments for FY 2013 will be approximately 5.17 percent of actual total MS–DRG payments, approximately 0.1 percentage point higher than the 5.1 percent we projected when setting the outlier policies for FY 2013. This estimate of 5.17 percent is based on simulations using the FY 2012 MedPAR file (discharge data for FY 2012 claims).

5. Proposed FY 2014 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) contain the proposed national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2014. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 69.6 percent, and Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the applicable percentage increase of 1.8 percent for FY 2014, and a proposed update of −0.2 percent for hospitals that fail to submit quality data consistent with section 1886(b)(3)(B)(viii) of the Act.

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 proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2014 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). This table also includes the proposed Puerto Rico standardized amounts. The proposed 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 proposed changes from the FY 2013 national standardized amount. The second column shows the proposed changes from the FY 2013 standardized amounts for hospitals that satisfy the quality data submission requirement and, therefore, receive the full proposed update of 1.8 percent. The third column shows the proposed changes for hospitals receiving the proposed reduced update of −0.2 percent. The first row of the table shows the proposed updated (through FY 2013) average standardized amount after restoring the FY 2013 offsets for outlier payments, demonstration budget neutrality, the geographic reclassification 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 wage index budget neutrality factors are cumulative. Therefore, those FY 2013 factors are not removed from this table.

COMPARISON OF FY 2013 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2014 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

	Full update (1.8 percent); wage index is greater than 1.0000; labor/non-labor share percentage (69.6/30.4)	Full update (1.8 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)	Reduced update (−0.2 percent); wage index is greater than 1.0000; labor/non-labor share percentage (69.6/30.4)	Reduced update (−0.2 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
FY 2013 Base Rate after removing: 1. FY 2013 Geographic Reclassification Budget Neutrality (0.991276) 2. FY 2013 Rural Community Hospital Demonstration Program Budget Neutrality (0.999677) 3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 (0.9478) 4. FY 2013 Operating Outlier Offset (0.948999)	Labor: $4,176.63 Nonlabor: $1,824.27	Labor: $3,720.56 Nonlabor: $2,280.34	Labor: $4,176.63 Nonlabor: $1,824.27	Labor: $3,720.56. Nonlabor: $2,280.34.
Proposed FY 2014 Update Factor	1.018	1.018	0.998	0.998.
Proposed FY 2014 MS–DRG Recalibration and Wage Index Budget Neutrality Factor.	0.997350	0.997350	0.997350	0.997350.
Proposed FY 2014 Reclassification Budget Neutrality Factor.	0.990971	0.990971	0.990971	0.990971.
Proposed FY 2014 Rural Community Demonstration Program Budget Neutrality Factor.	0.999834	0.999834	0.999834	0.999834.
Proposed FY 2014 Operating Outlier Factor.	0.948997	0.948997	0.948997	0.948997.
Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A.	0.998	0.998	0.998	0.998.
Cumulative Factor: FY 2008, FY 2009, FY 2012, and FY 2013 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Proposed Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9403	0.9403	0.9403	0.9403.

COMPARISON OF FY 2013 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2014 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE—Continued

	Full update (1.8 percent); wage index is greater than 1.0000; labor/non-labor share percentage (69.6/30.4)	Full update (1.8 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)	Reduced update (−0.2 percent); wage index is greater than 1.0000; labor/non-labor share percentage (69.6/30.4)	Reduced update (−0.2 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
Proposed National Standardized Amount for FY 2014.	Labor: $3,741.72 ..... Nonlabor: $1,634.32	Labor: $3,333.14 ..... Nonlabor: $2,042.90	Labor: $3,668.21 ..... Nonlabor: $1,602.21	Labor: $3,267.66. Nonlabor: $2,002.76.

The following table illustrates the proposed changes from the FY 2013 Puerto Rico-specific payment rate for hospitals located in Puerto Rico. The second column shows the proposed changes from the FY 2013 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index greater than 1.0000. The third column shows the proposed changes from the FY 2013 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index less than 1.0000. The first row of the table shows the proposed updated (through FY 2013) Puerto Rico-specific payment rate after restoring the FY 2013 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 factor is cumulative and is not removed from this table.

COMPARISON OF FY 2013 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE PROPOSED FY 2014 PUERTO RICO-SPECIFIC PAYMENT RATE

	Update (1.8 percent); wage index is greater than 1.0000; labor/non-labor share percentage (63.2/36.8)	Update (1.8 percent); wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
FY 2013 Puerto Rico Base Rate, after removing:		
1. FY 2013 Geographic Reclassification Budget Neutrality (0.991276)		
2. FY 2013 Rural Community Hospital Demonstration Program Budget Neutrality (0.999677)		
3. FY 2013 Puerto Rico Operating Outlier Offset (0.944760)	Labor: $1,700.33 ..... Nonlabor: $990.07.	Labor: $1,668.05. Nonlabor: $1,022.35.
Proposed FY 2014 Update Factor	1.018	1.018.
Proposed FY 2014 MS–DRG Recalibration Budget Neutrality Factor ...	0.997583	0.997583.
Proposed FY 2014 Reclassification Budget Neutrality Factor	0.990971	0.990971.
Proposed FY 2014 Rural Community Hospital Demonstration Program Budget Neutrality Factor.	0.999834	0.999834.
Proposed FY 2014 Puerto Rico Operating Outlier Factor	0.952600	0.952600.
Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A.	0.998	0.998.
Proposed Puerto Rico-Specific Payment Rate for FY 2014	Labor: $1,626.53 ..... Nonlabor: $947.09.	Labor: $1,595.64. Nonlabor: $977.98.

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the proposed labor-related and nonlabor-related shares that we used to calculate the proposed prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2014. 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. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national 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 proposed rule, we discuss the data and methodology for the proposed FY 2014 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make ''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. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at: *http://www.opm.gov/oca/cola/rates/asp* to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS proposed and final rules (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively), we explained that statutory changes transitioned the Alaska and Hawaii COLAs to locality pay. We further explained that, beginning in FY 2012, as OPM transitioned away from COLAs, we continued to use the same ''frozen'' COLA factors that were used to adjust payments in FY 2011 (based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion

of the standardized amount for hospitals located in Alaska and Hawaii while we explored alternatives for updating the COLA factors in the future. In the FY 2013 IPPS/LTCH PPS final rule, for FY 2013, we continued to use the same COLA factors used to adjust payments in FY 2012 (which are based on OPM's 2009 COLA factors). We also established a methodology to update the COLA factors for Alaska and Hawaii that were published by 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, we are proposing to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Specifically, under our methodology, we are using a comparison of the growth in the Consumer Price Indices (CPIs) in Anchorage and Honolulu relative to the growth in the overall CPI as published by the Bureau of Labor Statistics (BLS) to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28145 through 28146), because BLS publishes CPI data for only Anchorage, Alaska and Honolulu, Hawaii, our methodology for updating the COLA factors uses a comparison of the growth in the CPIs for those cities relative to the growth in the overall CPI to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are generally appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

The CPIs for ''All Items'' that BLS publishes for Anchorage, Alaska, Honolulu, Hawaii, and for the average U.S. city are based on a different mix of commodities and services than is reflected in the nonlabor related share of the IPPS market basket. As such, under the methodology we established to update the COLA factors, we calculated a ''reweighted CPI'' using the CPI for commodities and the CPI for services for each of the geographic areas to mirror the composition of the IPPS market basket nonlabor-related share. The current composition of BLS' CPI for ''All Items'' for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the nonlabor-related share of the proposed IPPS market basket is comprised of approximately 60 percent commodities and 40 percent services. We note that, if finalized, we do not anticipate that the proposals in section IV. of the preamble of this proposed rule (proposing to revise and rebase the IPPS market basket for FY 2014) would alter the commodities/services weights of the nonlabor-related share of the IPPS market basket. Therefore, under the methodology we established in the FY 2013 IPPS/LTCH PPS final rule, we have created reweighted indexes for Anchorage, Alaska, Honolulu, Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and applying the approximate 60/40 weights from the proposed IPPS market basket. We believe that this methodology is appropriate because we would continue to make a COLA adjustment for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor.

Under the COLA factor update methodology we established in the FY 2013 IPPS/LTCH PPS final rule, we further exercised our discretionary authority to adjust payments made to hospitals located in Alaska and Hawaii by incorporating a 25-percent cap on the CPI-updated COLA factors used to adjust the nonlabor-related portion of the standardized amounts, which is consistent with a statutorily mandated 25-percent cap that was applied to OPM's published COLA factors. We believe that this is appropriate because our proposed CPI-updated COLA factors for FY 2014 use the 2009 OPM COLA factors as a basis. In addition, we are proposing to continue to establish COLA factors that are rounded to 2 decimal places, which is consistent with the number of decimal places in the 2009 OPM COLA factors that are used as the basis for calculating the proposed FY 2014 COLA factors. This policy also would maintain consistency with the rounding used for the 25-percent cap on the COLA factors (that is, a COLA factor of no more than 1.25).

Applying this methodology, we are proposing to establish the COLA factors for FY 2014 that would adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii as shown in the table below.

PROPOSED FY 2014 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Proposed 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

Each of the COLA factors was calculated using data through 2012 as these are the latest historical CPI data published by the BLS. The reweighted CPI for Honolulu, Hawaii grew faster than the reweighted CPI for average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.9 percent and 8.3 percent, respectively. As a result, for FY 2014, we calculated proposed COLA factors for the City and County of Honolulu, the County of Kauai, the County of Maui, and the County of Kalawao to be 1.26 compared to the FY 2013 COLA factor of 1.25. However, as stated above, our COLA factor update methodology caps COLA factors at 1.25. In addition, the proposed COLA factor calculated for the County of Hawaii for FY 2014 is 1.19 compared to the FY 2013 COLA factor of 1.18.

The reweighted CPI for Anchorage, Alaska grew slower than the reweighted CPI for average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.0 percent and 8.3 percent, respectively. However, applying this slower relative growth rate to the FY 2009 COLA factors for each of the Alaska areas results in no proposed change to the COLA factors for the Alaska areas for FY 2014 (1.25 for ''All other'' areas of Alaska and 1.23 for the three specified urban areas of Alaska (Anchorage, Fairbanks and Juneau)) as compared to the FY 2013 COLA factors.

C. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2014

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs, for FY 2014 equals the Federal rate. (As noted above, due to the expiration of the MDH program, beginning with FY 2014, we are not including MDHs in our discussion of the update of the hospital-specific rates for FY 2014.)

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2014 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for hospitals located in Puerto Rico for FY 2014 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 (full update for hospitals submitting quality data; update including a −2.0 percent adjustment for hospitals that did not submit these data).

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 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).

The Federal 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 the formula described in section V.C. of the preamble of this proposed rule. Finally, 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.

2. Hospital-Specific Rate (Applicable Only to SCHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that currently SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs 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 equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increase to the hospital-specific rates applicable to SCHs is 1.8 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for MFP and less 0.3 percentage point) for hospitals that submit quality data or −0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less a proposed adjustment of 0.4 percentage point for MFP, and less 0.3 percentage point) for hospitals that fail to submit quality data. For a complete discussion of the applicable percentage increase applicable to the hospital-specific rates for SCHs, we refer readers to section V.A. of the preamble of this proposed rule.

In addition, because SCHs 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 hospital-specific rate is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.997583, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate an SCH will receive for its discharges beginning on or after October 1, 2013. We note that, in this proposed rule, for FY 2014, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposals 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. We note that section II.D. of the preamble of this proposed rule also includes a discussion on documentation and coding effects that occurred through FY 2010, including a request for public comments as to whether any portion of the proposed −0.8 percent recoupment adjustment discussed in section II.D.6. of the preamble of this proposed rule should be reduced and instead applied as a prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010.

c. Proposed Adjustment To Offset the Cost of the Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A Proposal and Clarification

As discussed previously, in section V.N.5. of the preamble of this proposed rule, our actuaries project additional IPPS expenditures would result from our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services (which is presented in section V.N.3. of the preamble of this proposed rule). We believe it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to propose reductions of 0.2 percent (or 0.998 adjustment) to the IPPS rates, including the proposed FY 2014 hospital-specific rate for SCHs, to offset our estimate of the increase in IPPS payments. We refer readers to section V.N. of the preamble of this proposed rule for a complete discussion of our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or After October 1, 2013, and Before October 1, 2014

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).

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).

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 average standardized amount.

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—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).

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 for a given discharge for a hospital located in Puerto Rico. This rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

c. Proposed Adjustment To Offset the Cost of the Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A Proposal and Clarification

As discussed previously, in section V.N.5. of the preamble of this proposed rule, our actuaries project additional IPPS expenditures would result from our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 ''midnights'') in the hospital receiving medically necessary services (which is presented in section V.N.3. of the preamble of this proposed rule). We believe it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to propose reductions of 0.2 percent (or 0.998 adjustment) to the IPPS rates, including the FY 2014 national standardized amount and the Puerto Rico standardized amount, to offset our estimate of the increase in IPPS payments. We refer readers to section V.N. of the preamble of this proposed rule for a complete discussion of our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2014

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 proposed capital Federal rate for FY 2014, which would be effective for discharges occurring on or after October 1, 2013.

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 Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2014. In particular, we explain why the proposed FY 2014 capital Federal rate would increase approximately 1.5 percent, compared to the FY 2013 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase 1.1 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 proposed update factor for FY 2014 under that framework is 0.9 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.2 percent increase in the proposed revised and rebased FY 2010-based CIPI (discussed in more detail in section IV.D. of the preamble of this proposed rule), 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 FY 2012 DRG reclassification and recalibration, and a forecast error correction of −0.3 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 2014 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2014.

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 2014, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will also equal 0.5 percent for FY 2014. The proposed net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the proposed net adjustment for case-mix change in FY 2014 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 2012 DRG reclassification and recalibration as part of our update for FY 2014. We estimate that FY 2012 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2014.

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. A forecast error of −0.3 percentage point was calculated for the proposed FY 2014 update. That is, current historical data indicate that the forecasted FY 2012 rate-of-increase of the FY 2006-based CIPI (1.5 percent) used in calculating the FY 2012 update factor slightly overstated the actual realized FY 2012 price increases of the FY 2006-based CIPI (1.2 percent) by 0.3 percentage point because the prices associated with both the depreciation and interest cost categories grew more slowly than anticipated. Historically, when 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. Therefore, we are proposing to make a −0.3 percentage point adjustment for forecast error in the update for FY 2014.

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 CIPI 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 proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2014 (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 2014, we are proposing to use an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2006 and extending through FY 2011. Based on these data, we estimated that case-mix constant intensity declined during FYs 2006 through 2011. 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 propose to continue to apply a zero intensity adjustment for FY 2014. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2014.

Above, we described the basis of the components used to develop the proposed 0.9 percent capital update factor under the capital update framework for FY 2014 as shown in the table below.

PROPOSED CMS FY 2014 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.2
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	−0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2012 Reclassification and Recalibration	0.0
Forecast Error Correction	−0.3
Total Update	0.9

*The capital input price index is based on the proposed revised and rebased FY 2010-based CIPI discussed in section IV.D. of the preamble of this proposed rule.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2013 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2014. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2013, Chapter 3.)

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 2013, we estimated that outlier payments for capital will equal 6.38 percent of inpatient capital-related payments based on the capital Federal rate in FY 2013. Based on the proposed thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs would equal 5.49 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2014. Therefore, we are proposing to apply an outlier adjustment factor of 0.9451 in determining the proposed capital Federal rate for FY 2014. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2014 will be somewhat lower than the percentage for FY 2013. This decrease in estimated capital outlier payments is primarily due to the proposed increase in the outlier threshold used to identify outlier cases for both inpatient operating and inpatient capital-related payments, which is discussed in section II.A. of this Addendum.

That is, because the outlier threshold used to identify outlier cases would be higher, cases would receive lower outlier payments and fewer cases would qualify for outlier payments.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2014 outlier adjustment of 0.9451 is a 0.95 percent change from the FY 2013 outlier adjustment of 0.9362. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2014 is 1.0095 (0.9451/0.9362). Thus, the proposed outlier adjustment would increase the FY 2014 capital Federal rate by 0.95 percent compared to the FY 2013 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. 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 proposed factors for FY 2014, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2013 MS–DRG classifications and relative weights and the FY 2013 GAF to estimated aggregate capital Federal rate payments based on the FY 2013 MS–DRG classifications and relative weights and the proposed FY 2014 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9998 for FY 2014 to the previous cumulative FY 2013 adjustment factor of 0.9904, yielding an adjustment factor of 0.9902 through FY 2014. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9990 for FY 2014 to the previous cumulative FY 2013 adjustment factor of 1.0095, yielding a cumulative adjustment factor of 1.0084 through FY 2014.

We then compared estimated aggregate capital Federal rate payments based on the FY 2013 MS–DRG relative weights and the proposed FY 2014 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2014 MS–DRG classifications and relative weights and the proposed FY 2014 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9990 both nationally and for Puerto Rico. The proposed cumulative adjustment factors for MS–DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2014 are 0.9892 nationally and 1.0074for 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 proposed cumulative adjustment factor accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs. It also incorporates the effects on the proposed GAFs of FY 2014 geographic reclassification decisions made by the MGCRB compared to FY 2013 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2014

For FY 2013, we established a capital Federal rate of $425.49 (77 FR 53706). We are proposing to establish an update of 0.9 percent in determining the FY 2014 capital Federal rate for all hospitals. In addition, as discussed in greater detail in section IV.C. of the preamble of this proposed rule, we are proposing to make a reduction of 0.2 percent to the capital IPPS rates, to offset the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

As a result of the proposed 0.9 percent update, the proposed budget neutrality factors, and the proposed 0.2 percent reduction to offset the estimated additional IPPS expenditures projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services discussed above, we are proposing to establish a national capital Federal rate of $432.03 for FY 2014. The proposed national capital Federal rate for FY 2014 was calculated as follows:

- The proposed FY 2014 update factor is 1.009, that is, the proposed update is 0.9 percent.
- The proposed FY 2014 budget neutrality adjustment factor that is applied to the proposed capital Federal rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs is 0.9988.
- The proposed FY 2014 outlier adjustment factor is 0.9451.
- A proposed adjustment factor of 0.9980 (that is, a reduction of 0.2 percent) to offset the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

(We note, in section VI.D. of the preamble of this proposed rule, we discuss the MS–DRG documentation and coding adjustment, including our proposed −0.8 percent recoupment adjustment to the operating IPPS standardized amount in FY 2014 under the provisions of section 631 of the ATRA, as well as additional prospective adjustments for the MS–DRG documentation and coding effect through FY 2010 authorized under section 1886(d)(3)(A)(vi) of the Act. Although we are not proposing an additional prospective adjustment in FY 2014 for the cumulative MS–DRG documentation and coding effects through FY 2010, we are soliciting public comments as to whether any portion of the proposed −0.8 percent recoupment adjustment to the operating IPPS standardized amount should be reduced and instead applied as a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS–DRG documentation and coding effect through FY 2010. We discuss in that same section that if we were to attribute a portion of the proposed −0.8 percent recoupment adjustment to the operating IPPS standardized amount for FY 2014 as a prospective adjustment, under the Secretary's broad authority under section 1886(g) of the Act, we also would make an appropriate adjustment to the national capital IPPS Federal rate (and note that the capital IPPS Puerto Rico rate would not be affected.)

Because the proposed 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 proposing to make additional adjustments in the capital Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS–DRG classifications and relative weights and for proposed changes in the GAFs. (As noted previously in this section, there is no need for an exceptions payment adjustment budget neutrality factor in determining the FY 2014 capital Federal rate.)

We are providing the following chart that shows how each of the proposed factors and proposed adjustments for FY 2014 affects the computation of the proposed FY 2014

national capital Federal rate in comparison to the FY 2013 national capital Federal rate. The proposed FY 2014 update factor has the effect of increasing the capital Federal rate by 0.9 percent compared to the FY 2013 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.12 percent. The proposed FY 2014 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.95 percent compared to the FY 2013 capital Federal rate. The proposed adjustment to account for the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A has the effect of decreasing the capital Federal rate by 0.2 percent compared to the FY 2013 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by 1.54 percent compared to the FY 2013 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2013 CAPITAL FEDERAL RATE AND PROPOSED FY 2014 CAPITAL FEDERAL RATE

	FY 2013	Proposed FY 2014	Change	Percent change
Update Factor [1]	1.0120	1.0090	1.0090	0.90
GAF/DRG Adjustment Factor [1]	0.9998	0.9988	0.9988	−0.12
Outlier Adjustment Factor [2]	0.9362	0.9451	1.0095	0.95
Adjustment for admission and medical review criteria [3]	N/A	0.9980	0.9980	−0.20
Capital Federal Rate	$425.49	$432.03	1.0154	1.54

[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 2013 to FY 2014 resulting from the application of the proposed 0.9988 GAF/DRG budget neutrality adjustment factor for FY 2014 is a net change of 0.9988 (or −0.12 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2014 outlier adjustment factor is 0.9451/0.9362, or 1.0095 (or 0.95 percent).

[3] The proposed adjustment to account for the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A (discussed in section VI.C. of the preamble of this proposed rule).

6. Proposed 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 proposed budget neutrality adjustment factors for the proposed national GAF and for the proposed Puerto Rico GAF, and the proposed budget neutrality factor for MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) is discussed above 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 2013, the special capital rate for hospitals located in Puerto Rico was $207.25 (77 FR 53707). With the changes we are proposing to make to the other factors used to determine the capital Federal rate (including the proposed adjustment to account for the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A (discussed in section V.N. of the preamble of this proposed rule), the proposed FY 2014 special capital rate for hospitals in Puerto Rico is $212.50.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2014

For purposes of calculating payments for each discharge during FY 2014, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2014 are in section II.A. of this Addendum. For FY 2014, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $24,140.

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 this proposed rule, we are proposing to rebase and revise the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV.D. of the preamble of this proposed rule. The CIPI was last rebased to FY 2006 in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021).

2. Forecast of the CIPI for FY 2014

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2013), we are forecasting the proposed FY 2010-based CIPI to increase 1.2 percent in FY 2014. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.8 percent increase in other capital expense prices in FY 2014, partially offset by a projected 2.3 percent decline in vintage-weighted interest expenses in FY 2014. The weighted average of these three factors produces the forecasted 1.2 percent increase for the proposed FY 2010-based CIPI as a whole in FY 2014.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2014

Historically, certain hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. An annual per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount for that period was multiplied by the Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to certain categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and cancer hospitals.

Payments for services furnished in children's hospitals and cancer hospitals that are excluded from the IPPS continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (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.)

We are proposing that the FY 2014 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, and RNHCIs would be the estimated percentage increase in the FY 2014 IPPS operating market basket, in accordance with applicable regulations at § 413.40. As described in section IV. of the preamble of this proposed rule, we are proposing to revise and rebase the IPPS operating market basket to a FY 2010 base year. Therefore, we are proposing to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for children's hospitals, 11 cancer hospitals, and RNHCIs for FY 2014 and subsequent fiscal years. Accordingly, the FY 2014 rate-of-increase percentage to be applied to the target amount for these cancer hospitals, children's hospitals, and RNHCIs would be the FY 2014 percentage increase in the FY 2010-based IPPS operating market basket. Based on IHS Global Insight, Inc.'s 2013 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2014 is 2.5 percent (that is, the estimate of the market basket rate-of-increase). We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2014.

IRFs, IPFs, and LTCHs were previously paid under the reasonable cost methodology. However, the statute was amended to provide for the implementation of prospective payment systems for IRFs, IPFs, and LTCHs. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provide transitioning periods of varying lengths of time during which a portion of the prospective payment was based on cost-based reimbursement rules under 42 CFR Part 413 (certain providers do not receive a transition period or may elect to bypass the transition as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that all of the various transitioning periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2014. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Updates to the Payment Rates for the LTCH PPS for FY 2014

A. Proposed LTCH PPS Standard Federal Rate for FY 2014

1. Background

In section VIII. of the preamble of this proposed rule, we discuss our proposed updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2014.

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. Thus, 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 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 and 2013, 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 VIII.C.2.b. of the preamble of this proposed 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 VIII.C.2.b. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2013, 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 2.6 percent and the 0.8 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(ix) of the regulations, we established an annual update of 1.8 percent to the standard Federal rate for FY 2013 (77 FR 53708 through 53711 and 53481).

For FY 2014, as discussed in greater detail in section VIII.C.2.e. of the preamble of this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal 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 0.3 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(D) of the Act. In addition, as discussed in greater detail in section VIII.C.2.c., beginning in FY 2014, the proposed annual update will be further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data in accordance with the LTCHQR Program under section 1886(m)(5) of the Act.

Specifically, in this proposed rule, based on the best available data, we are proposing to establish an annual update to the standard Federal rate of 1.8 percent provided the LTCH submits quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, which is based on the full estimated increase in the LTCH PPS market basket of 2.5 percent, less the proposed MFP adjustment of 0.4 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.3 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(D) of the Act. As discussed in greater detail in section VIII.C.2.c., for LTCHs that fail to submit quality reporting data for FY 2014 in accordance with the LTCHQR Program, the proposed annual update will be further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Accordingly, we are proposing an annual update to the LTCH PPS standard Federal rate of −0.2 percent for LTCHs that fail to submit quality reporting data for FY 2014. This is calculated based on the full estimated increase in the LTCH PPS market basket of 2.5 percent, less a proposed MFP adjustment of 0.4 percentage point, less an additional adjustment of 0.3 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 Proposed FY 2014 LTCH PPS Standard Federal Rate

We continue to believe that the annual update to the LTCH PPS standard Federal 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 2014, we applied the annual update to the LTCH PPS standard Federal rate from the previous year. In determining the proposed standard Federal rate for FY 2014, we also are proposing to make certain regulatory adjustments. Specifically, we are proposing to apply an adjustment factor under the second year of the 3-year phase-in of the one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3), as discussed in greater detail in section VIII.C.3. of the preamble of this proposed rule. In addition, in determining the proposed FY 2014 standard Federal rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53708 through 53710 and 53481), we established an annual update to the LTCH PPS standard Federal rate of 1.8 percent for FY 2013 based on the full estimated LTCH PPS market basket increase of 2.6 percent, less the MFP adjustment of 0.7 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(ix), we established an annual update to the standard Federal rate for FY 2013 of 1.8 percent. That is, we applied an update factor of 1.018 to the FY 2012 Federal rate of $40,222.05 to determine the FY 2013 standard Federal rate. Effective December 29, 2012, we also adjusted the standard Federal rate for FY 2013 by the one-time prospective adjustment factor for FY 2013 of 0.98734 under § 412.523(d)(3)(ii) (this adjustment was not applied to payments for discharges occurring before December 29, 2012, consistent with the statute). Furthermore, for FY 2013, we applied an area wage level budget neutrality factor of 0.999265 to the standard Federal 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) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, we established a standard Federal rate for FY 2013 of $40,397.96 (calculated as $40,222.05 × 1.018 × 0.98734 × 0.999265). Furthermore, consistent with the statute, the one-time prospective adjustment factor of 0.98734 applied to the standard Federal rate for FY 2013 is not applied to payments for discharges occurring before December 29, 2012. Thus, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, does not reflect that adjustment and instead are paid based on a standard Federal rate of $40,915.95 (calculated as $40,397.96 divided by 0.98734).

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.8 percent (that is, an update factor of 1.018) for FY 2014, based on the full estimated increase in the LTCH PPS market basket of 2.5 percent less the proposed MFP adjustment of 0.4 percentage point, consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.3 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(D) of the Act, provided the LTCH submits quality data in accordance with the LTCHQR Program under section 1886(m)(5) of the Act. Therefore, under proposed § 412.523(c)(3)(x), we are proposing to apply a factor of 1.018 to the FY 2013 standard Federal rate of $40,397.96 (as established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53710)) to determine the proposed FY 2014 standard Federal rate. For LTCHs that fail to submit quality reporting data for FY 2014 under the LTCHQR Program, under proposed § 412.523(c)(3)(x) in conjunction with proposed § 412.523(c)(4), we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by an additional 2.0 percentage points consistent with section 1886(m)(5) of the Act. Therefore, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of −0.2 percent (that is, 1.8 percent minus 2.0 percentage points = −0.2 percent or an update factor of 0.9980) for FY 2014 for LTCHs that fail to submit quality reporting data for FY 2014 under the LTCHQR Program. We also are proposing to establish that the standard Federal rate for FY 2014 would be further adjusted by a proposed adjustment factor of 0.98734 for FY 2014 under the second year of the 3-year phase-in of the one-time prospective adjustment at § 412.523(d)(3)(ii). In addition, for FY 2014, we are proposing to apply an area wage level budget neutrality factor of 1.000433 to the standard Federal rate to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, we are proposing to establish a standard Federal rate for FY 2014 of $40,622.06 (calculated as $40,397.96 × 1.018 × 0.98734 × 1.000433) for discharges occurring on or after October 1, 2013, and on or before September 30, 2014, provided the LTCH submits quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act. For LTCHs that fail to submit quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to establish a standard Federal rate for FY 2014 of $39,823.99 (calculated as $40,397.96 × 0.998 × 0.98734 × 1.000433) for discharges occurring on or after October 1, 2013, and on or before September 30, 2014.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2014

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 at § 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 index 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 wage index values are the full LTCH PPS 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. Proposed Geographic Classifications/Labor Market Area Definitions

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels, the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment at existing § 412.525(c) is made on the basis of the location of the LTCH in either an urban area or a rural area as defined in § 412.503. Currently under the LTCH PPS at § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (which would include 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.

In the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185), in regulations at § 412.525(c), we revised the labor market area definitions used under the LTCH PPS effective for discharges occurring on or after July 1, 2005, based on the Executive OMB's CBSA designations, which are based on 2000 Census data. We made this revision because we believe that the CBSA-based labor market area definitions will ensure that the LTCH PPS wage index 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 note that these are the same CBSA-based designations implemented for acute care hospitals under the IPPS at § 412.64(b) (69 FR 49026 through 49034). (For further discussion of the CBSA-based labor market area (geographic classification) definitions currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) We have generally updated the LTCH PPS CBSA-based labor market area definitions annually since they were adopted for RY 2006 when updates from OMB were available (73 FR 26812 through 26814, 74 FR 44023 through 44204, and 75 FR 50444 through 50445).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. We adopted those changes under the LTCH PPS in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), effective beginning October 1, 2010, and adopted their continued use for FY 2012 and FY 2013 (76 FR 51808 and 77 FR 53710, respectively). In the FY 2013 IPPS/LTCH PPS final rule, we explained that in 2013 OMB planned to announce new area delineations based on its 2010 standards and the 2010 Census data and, therefore, for the FY 2013 LTCH area wage level adjustment, we would continue to use the same labor market areas that we adopted for FY 2012 (77 FR 53710). In fact, on February 28, 2013, OMB issued OMB Bulletin No. 13–01, announcing revisions to the delineation of Metropolitan Statistical Areas, Micropolitian Statistical Areas, and Combined Statistical Areas, and guidance on uses of the delineation of these areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. According to OMB, this bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published in the **Federal Register** on June 28, 2010 (75 FR 37246 through 37252) and Census Bureau data.

In order to implement these changes for the LTCH PPS (as in the case of the IPPS, as discussed in section III.B. of the preamble of this proposed rule), it is necessary to identify the new area designations for each county and hospital in the country. While the revisions OMB published on February 28, 2013, are not as sweeping as the changes OMB announced in 2003, the February 28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart.

Because the update was not issued until February 28, 2013, and the changes made by the update and their ramifications must be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of this FY 2014 proposed rule. By the time the update was issued, the FY 2014 IPPS/LTCH PPS proposed rule was in the advanced stages of development. We had already developed the FY 2014 proposed LTCH PPS wage indexes based on the previous OMB definitions that are currently used under the LTCH PPS. We note that CMS was faced with a similar situation 10 years ago, when OMB announced changes resulting from the 2000 Census in June 2003. At that time, CMS proposed and implemented the changes under the IPPS for FY 2005, followed by the adoption under the LTCH PPS in RY 2006 (as noted previously). Similarly, to allow for sufficient time to assess the new changes and their ramifications, consistent with the proposal under the IPPS discussed in section III.B. of the preamble of this proposed rule, we intend to propose the adoption of the newest CBSA designations and the corresponding changes to the wage index based on those CBSA changes under the LTCH PPS for FY 2015 through notice and comment rulemaking. We refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191) for further information on the CBSA-based labor market area definitions currently used under the LTCH PPS. In addition, we refer readers to the FY 2005 IPPS final rule (69 FR 49026 through 49032) for those interested in learning about the issues that may need to be addressed in developing a proposal to implement the latest OMB update to the CBSA designations for FY 2015, and some of the policy decisions that may need to be taken into consideration in the development of such a proposal.

For FY 2014, we are proposing to continue to use the same labor market areas that were used under the LTCH PPS for FY 2013 (77 FR 53710) as we assess the new changes to the CBSA designations and their effect on LTCH PPS payments. This is consistent with the proposed approach being taken under the IPPS, and as noted previously, the LTCH PPS currently uses the same CBSA-based designations implemented for acute care hospitals under the IPPS.

3. Proposed LTCH PPS Labor-Related Share

Under the adjustment for differences in area wage levels at § 412.525(c), the labor-related share of a 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. Specifically, we determined the LTCH PPS labor-related share for FY 2013 based on the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and the labor-related share of capital costs of the LTCH-specific market basket based on FY 2009 data, as we believed these were the best data available to reflect the cost structure of LTCHs. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479 and 53710 through 53711), we established a labor-related share under the LTCH PPS for FY 2013 of 63.096 percent based on IGI's second quarter 2012 forecast of the FY 2009-based LTCH-specific market basket for FY 2013, as these were the most recent available data at that time that reflected the cost structure of LTCHs. (For additional details on the development of the LTCH PPS labor-related share for FY 2013, we refer readers to section VII.C.3.f. of the

preamble of the FY 2013 IPPS/LTCH PPS final rule.)

Consistent with our historical practice, we are proposing to determine the LTCH PPS labor-related share for FY 2014 based on the proposed FY 2014 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2009) and FY 2014. For this proposed rule, we are proposing to determine the LTCH PPS labor-related share for FY 2014 based on IGI's first quarter 2013 forecast of the FY 2009-based LTCH-specific market basket as this is currently the best available data. In addition, consistent with our proposal to update the labor-related share with the most recent available data, we are proposing that if more recent data become available, we would use those data in determining the labor-related share under the LTCH PPS for FY 2014 in the final rule.

The table below shows the proposed FY 2014 labor-related share relative importance using IGI's first quarter 2013 forecast of the FY 2009-based LTCH-specific market basket. The sum of the proposed relative importance for FY 2014 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, and All Other: Labor-related Services) would be 58.495 percent. We are proposing that the portion of capital-related costs that is influenced by the local labor market continue to be estimated to be 46 percent. Because the relative importance for capital-related costs would be 9.179 percent of the proposed FY 2009-based LTCH-specific market basket in FY 2014, we are proposing to take 46 percent of 9.179 percent to determine the proposed labor-related share of capital-related costs for FY 2014, which would result in 4.222 percent (0.46×9.179). We would then add that proposed 4.222 for the capital-related cost amount to the proposed 58.495percent for the operating cost amount to determine the total proposed labor-related share for FY 2014. Thus, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing a labor-related share under the LTCH PPS in FY 2014 of 62.717 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

PROPOSED FY 2014 LABOR-RELATED SHARE RELATIVE IMPORTANCE BASED ON THE FY 2009-BASED LTCH-SPECIFIC MARKET BASKET

	Proposed FY 2014 labor-related share relative importance
Wages and Salaries	45.130
Employee Benefits	8.134
Professional Fees: Labor-Related	2.214
Administrative and Business Support Services	0.502
All Other: Labor-Related Services	2.515
Subtotal	58.495
Labor-Related Portion of Capital Costs (46%)	4.222
Total Labor-Related Share	62.717

4. Proposed LTCH PPS Wage Index for FY 2014

Historically, under the LTCH PPS, we have established LTCH PPS 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 a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In the FY 2013 LTCH PPS final rule (77 FR 53711 through 53712), we calculated the FY 2013 LTCH PPS wage index values using the same data used for the FY 2013 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2009), 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 2013 LTCH PPS wage index values consistent with the urban and rural geographic classifications (labor market areas) 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 wage index values in areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable wage index values under the LTCH PPS for FY 2014, 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 adjustments under the LTCH PPS, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2010, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2010 data because these data are the most recent complete data available. These are the same data used to compute the proposed FY 2014 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. (For our rationale for using IPPS hospital wage data as a proxy for determining the wage index values used under the LTCH PPS, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44024 through 44025).)

The proposed FY 2014 LTCH PPS wage index values were computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this proposed rule and consistent with the pre-reclassified IPPS wage index policy (that is, 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 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 (as discussed in section III.G. of the preamble of this proposed rule). Furthermore, in determining the proposed FY 2014 LTCH PPS wage index values in this proposed rule, we are proposing to continue to use our existing policy for determining wage index values in areas where there are no IPPS wage data. We established a methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule, and we are proposing to continue to use this methodology for FY 2014. (We refer readers to the RY 2009 LTCH PPS final rule (73 FR 26817 through 26818) for an explanation of and rationale for our policy for determining LTCH PPS wage index values for areas that have no IPPS wage data.)

There are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2014. However, we calculate LTCH PPS wage index values for these areas using our established methodology in the event that, in the future, a LTCH should open in one of those areas. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is 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 is 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 2010 IPPS wage data that we used to determine the proposed FY 2014 LTCH PPS wage index values in this proposed rule, there are no IPPS wage data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2014 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660

and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS 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 FY 2010 IPPS wage data that we are using to determine the proposed FY 2014 LTCH PPS wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data for FY 2014. We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS wage data will vary in the future.

The proposed FY 2014 LTCH wage index values that would be applicable for LTCH discharges occurring on or after October 1, 2013, through September 30, 2014, 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 proposed rule and available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Changes to the 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 wage index values or labor-related share are 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 adjustment are budget neutral such that any changes to the wage index values or labor-related share will 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).)

As we did for FY 2013, in accordance with § 412.523(d)(4), for FY 2014, we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the standard Federal rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the standard Federal rate under § 412.523(d)(4) for FY 2014 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS payments using the FY 2013 wage index values (as established in Tables 12A and 12B listed in the Addendum to the FY 2013 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site) and the FY 2013 labor-related share of 63.096 percent (as established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479 and 53710 through 53711).

Step 2—We simulated estimated aggregate LTCH PPS payments using the proposed FY 2014 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the Internet on the CMS Web site) and the proposed FY 2014 labor-related share of 62.717 percent (based on the latest available data as discussed previously in section V.B.3. of this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2013 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2014 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2014.

Step 4—We then applied the proposed FY 2014 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2014 LTCH PPS standard Federal rate after the application of the proposed FY 2014 annual update (discussed in section V.A.2. of the Addendum to this proposed rule). For this proposed rule, using the steps in the methodology described above, we determined a proposed FY 2014 area wage level adjustment budget neutrality factor of 1.000433. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2014 LTCH PPS standard Federal rate, we are proposing to apply a proposed area wage level adjustment budget neutrality factor of 1.000433, in accordance with § 412.523(d)(4). The proposed FY 2014 LTCH PPS standard Federal rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

C. Proposed LTCH PPS Cost-of-Living Adjustment 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.

As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482 and 53712 through 53713), historically, we used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the LTCH PPS payments for LTCHs located in Alaska and Hawaii. Statutory changes have transitioned the Alaska and Hawaii COLAs to locality pay (phased in over a 3-year period beginning in January 2010, with COLA rates being frozen as of October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay). We explained that we did not believe it was appropriate to use either the 2010 or 2011 reduced COLA factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii for Medicare payment purposes. In addition, we believe that it was appropriate to use ''frozen'' COLA factors to adjust payments, while we explored alternatives for updating the COLA factors in the future.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53712 through 53713), we continued to use the same ''frozen'' COLA factors used in FY 2012 to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii in FY 2013 under § 412.525(b). In that same final rule, we also established a methodology to 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), beginning in FY 2014. The methodology we established to update the COLA factors is based on a 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 published by the Bureau of Labor Statistics (BLS). As also explained in that same final rule, we believe that using these updated COLA factors will appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii. (For additional details on the methodology we established in the FY 2013 IPPS/LTCH PPS final rule to update the COLA factors for Alaska and Hawaii beginning in FY 2014, we refer readers to section VII.D.3. of the preamble of that final rule (77 FR 53481 through 53482).)

In this proposed rule, for FY 2014, 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 adjustments under the LTCH PPS, we are proposing to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule for purposes of making a COLA for LTCHs located in Alaska and Hawaii under § 412.525(b). Specifically, the methodology uses a 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 published by the BLS. As discussed in that same final rule (77 FR 53481 through 53482), because BLS publishes CPI data for only Anchorage, Alaska and Honolulu, Hawaii, our methodology uses a comparison of the growth in the Consumer Price Indices (CPIs) for those cities relative to the growth in the

overall CPI to update the COLA factors for all areas located in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are generally appropriate and necessary proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

The ''CPI for All Items'' that BLS publishes for Anchorage, Honolulu, and for the average U.S. city are based on a different mix of commodities and services than is reflected in the nonlabor-related share of the IPPS market basket. We note that the mix of commodities and services for the nonlabor-related share based on the LTCH market basket is similar to that of the nonlabor-related share of the IPPS market basket. As such, under the methodology we established to update the COLA factors, we calculated a ''reweighted CPI'' using the CPI for commodities and the CPI for services for each of the geographic areas to mirror the composition of the IPPS market basket nonlabor-related share. Furthermore, we note that, if finalized, we do not anticipate that the proposals in section IV. of this preamble to revise and rebase the IPPS market basket for FY 2014 would alter the commodity/services weights for the nonlabor-related share of the IPPS market basket.

The current composition of BLS' CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the nonlabor-related share of the proposed IPPS market basket is comprised of approximately 60 percent commodities and 40 percent services. Therefore, under the methodology we established in the FY 2013 IPPS/LTCH PPS final rule we have created reweighted indexes for Anchorage, Alaska and Honolulu, Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and applying the approximate 60/40 weights from the proposed IPPS market basket. We believe that this method of reweighting is appropriate because we would continue to make a COLA for LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the LTCH PPS standard Federal rate by a COLA factor.

Under the COLA factor update methodology we established in the FY 2013 IPPS/LTCH PPS final rule, we further exercised our discretionary authority to adjust payments made to LTCHs located in Alaska and Hawaii by incorporating a 25-percent cap on the CPI-updated COLA factors used to adjust the nonlabor-related portion of the LTCH PPS standard Federal rate, which is consistent with a statutorily mandated 25-percent cap that was applied to OPM's published COLA factors. We believe that this is appropriate because our proposed CPI-updated COLA factors for FY 2014 uses the 2009 OPM COLA factors as a basis. In addition, we are proposing to continue to establish COLA factors that are rounded to 2 decimal places, which is consistent with the number of decimal places in the 2009 OPM COLA factors that are used as the basis for calculating the proposed FY 2014 COLA factors. This policy would also maintain consistency with the rounding used for the 25-percent cap on the COLA factors (that is, a COLA factor of no more than 1.25).

Applying this methodology, we are proposing to establish the COLA factors for FY 2014 that would adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii as shown in the table below.

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE LTCH PPS FOR FY 2014

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

Each of the COLA factors were calculated using data through 2012, as these are the latest historical CPI data published by the BLS. The reweighted CPI for Honolulu, Hawaii grew faster than the reweighted CPI for the average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.9 percent and 8.3 percent, respectively. As a result, for FY 2014, we calculated proposed COLA factors for the City and County of Honolulu, the County of Kauai, the County of Maui, and the County of Kalawao to be 1.26 compared to the FY 2013 COLA factor of 1.25. However, as stated above, our COLA factor update methodology caps the COLA factors at 1.25. In addition, the proposed COLA factor calculated for the County of Hawaii for FY 2014 is 1.19 compared to the FY 2013 COLA factor of 1.18.

The reweighted CPI for Anchorage, Alaska grew slower than the reweighted CPI for the average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.0 percent and 8.3 percent, respectively. However, applying this slower relative growth rate to the FY 2009 COLA factors for each of the Alaska areas results in no proposed change to the COLA factors for the Alaska areas for FY 2014 (1.25 for ''All other areas of Alaska'' and 1.23 for the three specified urban areas of Alaska (Anchorage, Fairbanks, and Juneau) as compared to the FY 2013 COLA factors.

D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. 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. 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 § 412.525(a) in the regulations (in conjunction with § 412.503), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the MS–LTC–DRG plus a fixed-loss amount. Specifically, in accordance with § 412.525(a)(3) (in conjunction with § 412.503), 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 Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under the outlier 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 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 (adjusted MS–LTC–DRG 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 LTCH PPS HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that a 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 a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

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 and SSO cases under the LTCH PPS, at § 412.525(a) and § 412.529, respectively. Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for both HCO and SSO cases (to determine the estimated cost of the case at § 412.529(d)(2)), we are discussing the determination of CCRs under the LTCH PPS for both of these types of cases simultaneously.

In determining both HCO payments (at § 412.525(a)) and SSO payments (at § 412.529), 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) and § 412.529(f)(4)(ii) for HCOs and SSOs, respectively. (We note that, in some instances, we use an alternative CCR, such as the statewide average CCR in accordance with the regulations at § 412.525(a)(4)(iv)(C) and § 412.529(f)(4)(iii), or a CCR that is specified by CMS or that is requested by the hospital under the provisions of the regulations at § 412.525(a)(4)(iv)(A) and § 412.529(f)(4)(i).) 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, a LTCH's CCR is calculated by dividing a 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, a LTCH is assigned the applicable statewide average CCR if, among other things, a 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, therefore, CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Thus, under our established policy, generally, if a 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 accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2012 update of the PSF, we are proposing to establish a total CCR ceiling of 1.259 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2013 through September 30, 2014. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data became available, we would use such data to establish a total CCR ceiling for FY 2014 in the 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) and the SSO policy at § 412.529(f)(4)(iii), the fiscal intermediary or MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for a 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 fiscal intermediary or MAC may consider in determining a 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 a LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2012 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2013 through September 20, 2014, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet). Furthermore, consistent with our historical practice of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for FY 2014 in the final rule. All areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of March 2013. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet).

In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of LTCH HCO and SSO Payments

We note that under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(D) and the LTCH PPS SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases, respectively, are subject to reconciliation. Specifically, any reconciliation of outlier 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. For additional information, 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. Establishment of the Proposed LTCH PPS Fixed-Loss Amount for FY 2014

When we implemented the LTCH PPS, as discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56026), 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. 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, to determine the outlier payment for each case, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under § 412.525(a)(3) (in conjunction with § 412.503), 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 Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53715), we presented our policies regarding the methodology and data we would use to establish the fixed-loss amount of $15,408 for FY 2013. In general, for FY 2014, we are proposing to continue to use our existing methodology to calculate a fixed-loss amount for FY 2014 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments (based on the rates and policies presented in that proposed rule). (For additional detail on the rationale for setting the HCO payment ''target'' at 8 percent of total estimated LTCH PPS payments, we refer readers to the FY 2003 LTCH PPS final rule (67 FR 56022 through 56024).) Using our existing methodology, we are proposing a fixed-loss amount of $14,139 for FY 2014.

In this proposed rule, we are proposing to continue to use our existing methodology to calculate the fixed-loss amount for FY 2014 (based on the data and the rates and policies presented in this proposed 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 2014, we are proposing to use the most recent available LTCH claims data and CCR data at this time. Specifically, for this proposed rule, we are proposing to use LTCH claims data from the December 2012 update of the FY 2012 MedPAR file and CCRs from the December 2012 update of the PSF to determine a fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2014 because these data are the most recent complete LTCH data available at this time.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are proposing to establish a fixed-loss amount of $14,139 for FY 2014. Thus, we are proposing to make 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 outlier threshold (the sum of the adjusted Federal LTCH payment for the MS–LTC–DRG and the fixed-loss amount of $14,139). We also note that the proposed fixed-loss amount of $14,139 for FY 2014 is lower than the FY 2013 fixed-loss amount of $15,408. Based on our payment simulations using the most recent available data at this time, the decrease in the proposed fixed-loss amount for FY 2014 is necessary to maintain the existing requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments. (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 less than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases. In addition, maintaining the higher fixed-loss amount would result in a decrease in the amount of the additional payment for an HCO case because the maximum loss that a LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be larger. For these reasons, we believe that lowering the fixed-loss amount is appropriate and necessary to maintain that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments as required under § 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case. 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. Thus, for an SSO case in FY 2014, the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $14,139 and the amount paid under the SSO policy as specified in § 412.529).

E. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2014

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal rate. Under § 412.525(c), the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the applicable LTCH PPS wage index (proposed FY 2014 values are shown in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule and are available via the Internet). The standard Federal rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2014 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish a standard Federal rate for FY 2014 of $40,622.06 (provided the LTCH submits quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act), as discussed above in section V.A.2. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS Federal standard rate for FY 2014 in the following example:

Example: During FY 2014, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974) and discharged on January 1, 2014. The proposed FY 2014 LTCH PPS wage index value for CBSA 16974 is 1.0446 (obtained from Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The Medicare patient is classified into MS–LTC–DRG 28 (Spinal Procedures with MCC), which has a relative weight for FY 2014 of 1.6023 (obtained from Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient in FY 2014, we compute the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted proposed FY 2014 standard Federal rate ($40,622.06, for LTCHs that submit quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act) by the proposed labor-related share (62.717 percent) and the proposed wage index value (1.0446). This wage-adjusted amount is then added to the proposed nonlabor-related portion of the unadjusted proposed standard Federal rate (37.283 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed Federal rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (1.6023) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2014 ($66,909.36). The table below illustrates the components of the calculations in this example.

Unadjusted Proposed Standard Federal Prospective Payment Rate (provided the LTCH submits quality data in accordance with the LTCHQR Program under section 1886(m)(5) of the Act)	$40,622.06
Proposed Labor-Related Share	× 0.62717
Labor-Related Portion of the Proposed Federal Rate	= $25,476.94
Proposed Wage Index (CBSA 16974)	× 1.0446
Proposed Wage-Adjusted Labor Share of Federal Rate	= $26,613.21
Proposed Nonlabor-Related Portion of the Federal Rate ($40,622.06 × 0.37283)	+ $15,145.12
Adjusted Proposed Federal Rate Amount	= $41,758.33

Proposed MS–LTC–DRG 28 Relative Weight	× 1.6023
Total Adjusted Proposed Federal Prospective Payment	= $66,909.37

VI. Tables Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 and 2013, for the FY 2014 rulemaking cycle, the IPPS and LTCH tables will not be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings and will be available only through the Internet. Specifically, IPPS Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, Supplement to 5, 6G, 6H, 6I, 6J, 6K, 7A, 7B, 8A, 8B, 9A, 9C, 10, 15, and 16 and LTCH PPS Tables 8C, 11, 12A, 12B, 13A, and 13B will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, displayed at the end of this section, will continue to be published in the **Federal Register** as part of the annual proposed and final rules. As discussed in section II.G.9. and 11. of the preamble of this proposed rule, Tables 6A through 6F will not be issued with this FY 2014 proposed rule because there are no changes to the ICD–9–CM codes. As discussed in section V.C. of the preamble of this proposed rule, effective FY 2014 and forward, the low-volume hospital definition and payment adjustment methodology under section 1886(d)(12) of the Act returns to the pre-Affordable Care Act definition and payment adjustment methodology (we refer readers to section V.C. for complete details on the low-volume hospital payment adjustment). Therefore, we are no longer including a table (previously Table 14) in this proposed rule that lists the low-volume payment adjustments.

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 2014 proposed 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 2014 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''.

Table 2.—Proposed Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2012; Proposed Hospital Wage Indexes for Federal Fiscal Year 2014; Hospital Average Hourly Wages for Federal Fiscal Years 2012 (2008 Wage Data), 2013 (2009 Wage Data), and 2014 (2010 Wage Data); and 3-Year Average of Hospital Average Hourly Wages

Table 3A.—Proposed FY 2014 and 3-Year* Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—Proposed FY 2014 and 3-Year* Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2014

Table 4B.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2014

Table 4C.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2014

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 Proposed Statewide Rural Floor or Imputed Floor Wage Index—FY 2014

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2014

Table 4F.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2014

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2014

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2014

Supplement to Table 5—List of MS–DRGs and Relative Weighting Factors Using 15 Cost-to-Charge Ratios (Not Proposed)—FY 2014

Table 6G.—Proposed Additions to the CC Exclusions List—FY 2014

Table 6H—Proposed Deletions from the CC Exclusions List—FY 2014

Table 6I.—Proposed Major CC List—FY 2014

Table 6J.—Proposed Complete CC List—FY 2014

Table 6K.—Proposed Complete List of CC Exclusions—FY 2014

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2012 MedPAR Update—December 2012 GROUPER V30.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2012 MedPAR Update—December 2012 GROUPER V31.0 MS–DRGs

Table 8A.—Proposed FY 2014 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2014 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations—FY 2014

Table 9C.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act—FY 2014

Table 10.—Proposed New Technology Add-On Payment Thresholds [1 2] for Applications for FY 2015

Table 15.—Proposed FY 2014 Proxy Readmissions Adjustment Factors

Table 16.—Proposed Proxy Hospital Inpatient Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2014

The following LTCH PPS tables for this FY 2014 proposed 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–1599–P.

Table 8C.—Proposed FY 2014 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, Short-Stay Outlier (SSO) Threshold, and ''IPPS Comparable Threshold'' for Discharges Occurring from October 1, 2013 through September 30, 2014 under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2013 through September 30, 2014

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2013 through September 30, 2014

Table 13A.—Proposed Composition of Low-Volume Quintiles for MS–LTC–DRGs—FY 2014

Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2014

TABLE 1A—PROPOSED 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 2014

Full update (1.8 percent)		Reduced update (−0.2 percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,741.72	$1,634.32	$3,668.21	$1,602.21

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2014

Full update (1.8 percent)		Reduced update (−0.2 percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,333.14	$2,042.90	$3,267.66	$2,002.76

TABLE 1C—PROPOSED 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 2014

	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
Standardized amount	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$3,333.14	$2,042.90
Puerto Rico	$1,626.53	$947.09	1,595.64	977.98

[1] For FY 2014, there are no CBSAs in Puerto Rico with a proposed national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2014

	Rate
National	$432.03

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2014—Continued

	Rate
Puerto Rico	212.50

TABLE 1E—PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE—FY 2014

	Full update (1.8 percent)	Reduced update* (−0.2 percent)
Standard Federal Rate	$40,622.06	$39,823.99

* For LTCHs that fail to submit quality reporting data for FY 2014 in accordance with the LTCH Quality Reporting Program, the proposed 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 proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (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 proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2014 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 proposed payment changes in this proposed rule, would result in an estimated $110 million decrease in FY 2014 operating payments (or −0.1 percent change) and an estimated $101 million increase in FY 2014 capital payments (or 1.1 percent change). These proposed changes are relative to payments made in FY 2013. The impact analysis of the proposed capital payments can be found in section I.K. of this Appendix. In addition, as described in section I.L. of this Appendix, LTCHs are expected to experience an increase in payments by $62 million in FY 2014 relative to FY 2013.

Our operating impact estimate includes the proposed −0.8 percent documentation and coding adjustment applied to the IPPS standardized amount, as part of the recoupment required under section 631 of the ATRA. It includes the proposed −0.2 percent adjustment applied to the IPPS standardized amount, the hospital-specific rate, and the Puerto Rico-specific rate to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A. In addition, our operating payment impact estimate includes the proposed 1.8 percent hospital update to the standardized amount (which includes the estimated 2.5 percent market basket update less 0.4 percentage point for the proposed multifactor productivity adjustment and less 0.3 percentage point required under the Affordable Care Act). The estimates of proposed IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed

rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

B. Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS 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 the proposed changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes 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 proposed policy changes, as well as statutory changes effective for FY 2014, 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 31 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, 45 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of March 2013, there are 3,404 IPPS acute care hospitals included in our analysis. This represents approximately 55 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,328 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, and 11 cancer hospitals, which are paid under separate payment systems. 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 proposed rule. The impact of the proposed update and proposed policy changes to the LTCH PPS for FY 2014 is discussed in section I.L. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2013, there were 97 children's hospitals, 11 cancer hospitals, and18 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, 234 rehabilitation hospitals and 898 rehabilitation units, and 437 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 472 psychiatric hospitals and 1,155 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 proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.L. of this Appendix.

For children's hospitals, the 11 cancer hospitals, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2014 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 this proposed rule, we are proposing to rebase the IPPS operating market basket to a FY 2010 base year. Therefore, we are proposing to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2014 and subsequent years for children's hospitals, the 11 cancer hospitals, 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 2013 first quarter forecast of the proposed FY 2010-based market basket increase, we are estimating that the proposed FY 2014 update based on the IPPS operating market basket is 2.5 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 proposed to be 0.4 percentage point) and a 0.3 percentage point reduction to the market basket update resulting in a proposed 1.8 percent applicable percentage increase for IPPS hospitals subject to a reduction of 2.0 percentage points if the hospital fails to submit quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. Children's hospitals, the 11 cancer hospitals, 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 RNHCIs, children's hospitals, and the 11 cancer hospitals paid under § 413.40 of the regulations, the proposed update is the proposed percentage increase in the FY 2014 IPPS operating market basket, estimated at 2.5 percent, without the reductions required under the Affordable Care Act.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that 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 Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and proposed payment rate updates for the IPPS for FY 2014 for operating costs of acute care hospitals. The proposed FY 2014 updates to the capital payments to acute care hospitals are discussed in section I.K. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2014 operating payments will decrease by 0.1 percent compared to FY 2013. In addition to the applicable percentage increase, this amount reflects the proposed FY 2014 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this proposed rule and the proposed adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A: a −0.8 percent adjustment to the IPPS national standardized amounts for the proposed documentation and coding adjustment and a −0.2 percent adjustment to the IPPS national standardized amount, the Puerto Rico-specific rate and the hospital-specific rate for the policy proposal on admission and medical review criteria. 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 proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this proposed rule. However, there are other proposed changes for which we do not have data available that will allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented below are taken from the FY 2012 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each 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 2012 MedPAR file, we simulated proposed 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 proposed 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. Proposed estimated payment impacts of the capital IPPS for FY 2014 are discussed in section I.K. of this Appendix.

We discuss the following proposed changes below:

- The effects of the application of the proposed documentation and coding adjustment, the proposed adjustment to offset the costs of the policy proposal on admission and medical review criteriaand the proposed 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 proposed changes to the relative weights and MS–DRG grouper, including the proposed methodology to calculate the MS–DRG cost based relative weights using 19 departmental CCRs instead of the current 15 departmental CCRs.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2010, compared to the FY 2009 wage data and the proposed changes in the labor related share from 68.8 percent for FY 2013 to the proposed 69.6 percent for FY 2014 for hospitals with a wage index greater than 1.0.
- The effects of the proposed recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the proposed wage and recalibration budget neutrality factors.
- The effects of the geographic reclassifications by the MGCRB as of publication of this proposed rule that would be effective for FY 2014.
- The effects of the proposed rural floor and imputed floor with the application of the national budget neutrality factor applied to the wage index.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States cannot have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the proposed implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.
- The effects of the proposed policies for implementation of the Hospital Readmissions Reduction Program under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, that adjusts hospital's base operating DRG amount by an adjustment factor to account for a hospital's excess readmissions.
- The effects of the expiration of the special payment status for MDHs under section 606 of the ATRA under which MDHs that currently receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate will be paid based on the Federal standardized amount starting in FY 2014.
- The effects of the proposed implementation of section 3133 of the Affordable Care Act that reduces Medicare DSH payments to 25 percent of what hospitals had been previously paid under section 1886(d)(5)(F) of the Act and establishes an additional payment to be made to hospitals that receive DSH payments for their relative share of the total amount of uncompensated care.
- The total estimated change in payments based on the proposed FY 2014 policies relative to payments based on FY 2013 policies that include the applicable percentage increase of 1.8 percent (or 2.5 percent market basket update with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and a 0.3 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2014 changes, our analysis begins with a FY 2013 baseline simulation model using: the proposed FY 2014 applicable percentage increase of 1.8 percent and the proposed documentation and coding adjustment of 0.8 percent to the Federal standardized amount and the proposed adjustment 0.2 percent to the Federal standardized amount, the hospital-specific rate, and the Puerto Rico-specific rate for the policy proposal on admission and medical review criteria; the FY 2013 MS–DRG GROUPER (Version 30.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2013 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, 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.) At the time that this impact was prepared, 52 hospitals did not receive the full market basket rate-of-increase for FY 2013 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2014 using a reduced update for these 52 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2014.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2014 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our final comparison illustrates the proposed percent change in payments per case from FY 2013 to FY 2014. 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 proposing to update the standardized amounts for FY 2014 using a proposed applicable percentage increase of 1.8 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.5 percent with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment and a 0.3 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements would receive a proposed update of −0.2 percent (this proposed update includes the 2.0 percentage point reduction for failure to submit these data)). Under section 1886(b)(3)(B)(iv) of the Act, the updates to

the hospital-specific amounts for SCHs also are equal to the applicable percentage increase, or 1.8 percent. In addition, we are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 1.8 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2013 to FY 2014 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 2013 that are no longer reclassified in FY 2014. Conversely, payments may increase for hospitals not reclassified in FY 2013 that are reclassified in FY 2014.

A third significant factor is that we currently estimate that actual outlier payments during FY 2013 will be 5.2 percent of total MS–DRG payments. When the FY 2013 final rule was published, we projected FY 2013 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 higher than expected outlier payments during FY 2013 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current estimates of FY 2013 payments per case to estimated FY 2014 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 proposed changes for FY 2014. 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 3,404 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 2,481 hospitals located in urban areas included in our analysis. Among these, there are 1,367 hospitals located in large urban areas (populations over 1 million), and 1,114 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 923 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 2013 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 2,495; 1,377; 1,118; and 909, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,378 nonteaching hospitals in our analysis, 782 teaching hospitals with fewer than 100 residents, and 244 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 five rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, RRCs, and former MDHs). There were 207 RRCs, 329 SCHs, 192 former MDHs, and 124 hospitals that are both SCHs and RRCs, and 11 hospitals that were former 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 2011 or FY 2010 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 2014. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the proposed policy changes on the 15 cardiac hospitals.

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2014

	Number of hospitals [1] (1)	Proposed hospital rate update and documentation and coding adjustment [2] (2)	Proposed FY 2014 weights and DRG changes with application of recalibration budget neutrality [3] (3)	Proposed FY 2014 wage data with application of wage budget neutrality [4] (4)	Proposed FY 2014 DRG, rel. wts., wage index changes with wage and recalibration budget neutrality [5] (5)	Proposed FY 2014 MGCRB reclassifications [6] (6)	Proposed rural floor and imputed floor with application of national rural floor budget neutrality [7] (7)	Proposed application of the frontier wage index [8] (8)	Proposed FY 2014 outmigration adjustment [9] (9)	Expiration of MDH status [10] (10)	Proposed hospital readmissions reduction program [11] (11)	Proposed changes to Medicare DSH [12] (12)	All proposed FY 2014 changes [13] (13)
All Hospitals	3,404	0.8	0	0	0.1	0	0	0.1	0	−0.1	−0.2	−0.9	−0.1
By Geographic Location													
Urban hospitals	2481	0.8	0	0	0.1	−0.2	0	0.1	0	0	−0.2	−0.8	0.1
Large urban areas	1367	0.8	0	0.1	0.2	−0.3	0	0	0	0	−0.2	−0.7	0.5
Other urban areas	1114	0.8	0.1	−0.1	0	−0.1	0.1	0.2	0	−0.1	−0.1	−1.1	−0.4
Rural hospitals	923	1.2	−0.5	−0.2	−0.6	1.7	−0.3	0.1	0.1	−1.2	−0.2	−0.9	−1.9
Bed Size (Urban)													
0–99 beds	622	0.8	0.3	0	0.3	−0.4	0.1	0.2	0	−0.4	−0.1	0.6	0.9
100–199 beds	762	0.8	−0.1	0	−0.1	−0.1	0.3	0.1	0	0	−0.2	−1.1	−0.5
200–299 beds	464	0.8	−0.1	0	0	0	0	0.1	0	0	−0.2	−0.7	−0.1
300–499 beds	418	0.8	0.1	0	0.1	−0.2	0	0.1	0	0	−0.2	−0.8	0.1
500 or more beds	215	0.8	0.2	0.1	0.4	−0.2	−0.1	0	0	0	−0.2	−1	0.4
Bed Size (Rural)													
0–49 beds	339	1.1	−0.8	−0.3	−1	0.5	−0.3	0.1	0.2	−2	−0.3	0.3	−2.4
50–99 beds	328	1.2	−0.7	−0.2	−0.8	1.2	−0.3	0	0.2	−3.3	−0.3	−0.1	−3.3
100–149 beds	151	1.2	−0.6	−0.3	−0.7	1.9	−0.3	0.1	0	−0.3	−0.3	−1	−1.1
150–199 beds	59	1.1	−0.2	−0.2	−0.3	2.2	−0.4	0.1	0	0	−0.2	−1.5	−1.1
200 or more beds	46	1.2	−0.1	−0.3	−0.2	2.4	−0.3	0	0	0	−0.2	−1.9	−1.2
Urban by Region													
New England	120	0.8	−0.1	0.4	0.4	0.7	4.4	0	0	0	−0.2	−1.5	0.2
Middle Atlantic	318	0.8	0	0.7	0.7	0.3	−0.3	0	0	0	−0.3	−0.1	1.6
South Atlantic	375	0.8	0	−0.4	−0.3	−0.4	−0.4	0	0	−0.1	−0.1	−0.4	0
East North Central	395	0.8	0	−0.2	−0.1	−0.2	−0.5	0	0	0	−0.2	−0.7	−0.2
East South Central	149	0.8	0.1	−0.5	−0.2	−0.3	−0.4	0	0	0	−0.2	−0.9	−0.3
West North Central	165	0.8	0.2	−0.2	0	−0.7	−0.5	0.8	0	−0.1	−0.1	−0.8	−0.2
West South Central	371	0.8	0.1	−0.3	0	−0.6	−0.5	0	0	0	−0.1	−0.8	−0.1
Mountain	156	0.9	0.2	−0.1	0.1	−0.1	0	0.2	0	0	−0.1	0.8	1.2
Pacific	381	0.8	0	0.5	0.5	−0.1	0.7	0	0	0	−0.1	−3.2	−1.5
Puerto Rico	51	1	−0.1	0.2	0.5	−0.8	0	0	0	0	0	34.5	35.7
Rural by Region													
New England	23	1	−0.3	0.2	−0.1	3.2	−0.5	0	0	−3.9	0	−0.8	−2.9
Middle Atlantic	69	1.2	−0.5	−0.2	−0.6	1.6	−0.3	0	0.1	−2.1	−0.2	0.3	−1.2
South Atlantic	165	1.1	−0.5	−0.3	−0.7	2.1	−0.4	0	0.1	−1	−0.3	−0.9	−1.8
East North Central	119	1.2	−0.3	−0.3	−0.6	1.3	−0.3	0	0.1	−2.1	−0.2	−0.3	−1.6
East South Central	171	0.9	−0.4	−0.5	−0.7	2.5	−0.5	0	0.1	−0.6	−0.4	−2	−3.5
West North Central	100	1.4	−0.3	0.1	−0.2	0.4	−0.1	0.3	0.1	−0.8	−0.1	−0.7	−0.4
West South Central	181	1	−0.6	−0.5	−0.9	2.2	−0.4	0	0.1	−0.4	−0.4	−1.2	−2.7
Mountain	65	1.5	−0.4	−0.1	−0.4	0.2	−0.1	0.4	0	−0.1	−0.1	−0.9	0
Pacific	29	1.4	−0.6	0.2	−0.4	1.1	−0.2	0	0	−0.1	−0.1	−0.7	−0.3
Puerto Rico	1	1	3.3	−0.5	3.4	−0.9	−0.4	0	0	0	0	0	4.6

By Payment Classification													
Urban hospitals	2495	0.8	0	0	0.1	−0.2	0	0	0	0	−0.2	−0.8	0.1
Large urban areas	1377	0.8	0	0.1	0.2	−0.2	0	0	0	0	−0.2	−0.7	0.5
Other urban areas	1118	0.8	0.1	−0.1	0	0	0.1	0.1	0	0	−0.1	−1.1	−0.4
Rural areas	909	1.2	−0.4	−0.2	−0.6	1.4	−0.3	0.2	0.1	−1.2	−0.2	−0.9	−1.9
Teaching Status													
Nonteaching	2378	0.9	−0.1	−0.1	−0.2	0.2	0	0	0	−0.3	−0.2	−0.9	−0.8
Fewer than 100 residents	782	0.8	0	0	0	−0.1	0	0.1	0	0	−0.1	−0.9	−0.1
100 or more residents	244	0.8	0.2	0.2	0.5	−0.2	0	0	0	0	−0.2	−0.7	0.8
Urban DSH													
Non-DSH	706	0.8	0	0	0.1	0.1	0	0	0	−0.2	−0.2	0	0.2
100 or more beds	1562	0.8	0.1	0	0.1	−0.2	0	0	0	0	−0.2	−1	0
Less than 100 beds	330	0.9	−0.4	0.1	−0.3	0.2	0.1	0.2	0	−0.5	−0.2	1.1	1.2
Rural DSH													
SCH	260	1.5	−0.8	0	−0.8	0.1	−0.1	0	0	−0.2	−0.2	−0.1	−1.3
RRC	223	1.2	−0.3	−0.2	−0.4	2	−0.3	0.4	0	−0.3	−0.2	−1.9	−1.6
100 or more beds	29	0.8	−0.5	−0.3	−0.6	1.2	−0.4	0	0.1	−1.5	−0.3	1.5	0.2
Less than 100 beds	294	0.8	−0.7	−0.5	−0.9	0.8	−0.5	0	0.4	−4.9	−0.4	1.1	−3.6
Urban teaching and DSH													
Both teaching and DSH	826	0.8	0.1	0.1	0.3	−0.3	0	0.1	0	0	−0.2	−0.9	0.4
Teaching and no DSH	135	0.8	0	0.2	0.2	0.3	0.1	0	0	0	−0.2	0	0.7
No teaching and DSH	1066	0.8	−0.1	−0.1	−0.1	0	0.2	0	0	0	−0.2	−1.2	−0.6
No teaching and no DSH	468	0.8	0.1	0	0.1	−0.2	−0.1	0.1	0	0	−0.2	0	0.3
Special Hospital Types													
RRC	207	0.8	−0.1	−0.1	−0.1	2.9	−0.4	0.5	0.1	−0.5	−0.2	−1.9	−1.4
SCH	329	1.5	−0.6	0	−0.6	0	−0.1	0	0	−0.1	−0.2	−0.2	−0.5
Former MDH	192	0.8	−0.7	−0.6	−1.1	1.1	−0.4	0	0.3	−9.9	−0.5	0.3	−8.5
SCH and RRC	124	1.5	−0.3	0	−0.3	0.5	−0.1	0	0	0	−0.2	−1.1	−0.1
Former MDH and RRC	11	0.8	−0.4	0.3	0	2	−0.6	0	0.1	−15.7	−0.2	−0.8	−12.4
Type of Ownership													
Voluntary	1944	0.8	0	0.1	0.1	0	0	0.1	0	−0.1	−0.2	−0.9	−0.1
Proprietary	895	0.8	0.1	−0.1	0	0.1	0	0.1	0	−0.1	−0.2	−1.4	−0.9
Government	546	0.9	0	−0.2	−0.1	−0.1	−0.1	0	0	−0.1	−0.1	0.3	1.1
Medicare Utilization as a Percent of Inpatient Days													
0–25	368	0.8	0.2	0.3	0.5	−0.3	−0.1	0	0	0	−0.1	4.4	6
25–50	1807	0.8	0.1	0	0.1	−0.2	0	0.1	0	0	−0.2	−1.5	−0.6
50–65	967	0.9	−0.2	−0.1	−0.2	0.6	0.1	0	0	−0.4	−0.2	−0.9	−0.8
Over 65	171	1	−0.4	−0.3	−0.7	0.8	−0.3	0	0.1	−1.6	−0.4	−0.6	−1.9
FY 2014 Reclassifications by the Medicare Geographic Classification Review Board													
All Reclassified Hospitals	762	0.9	−0.1	0	0	2.1	0.2	0	0	−0.2	−0.2	−1.2	−0.5
Non-Reclassified Hospitals	2642	0.8	0	0	0.1	−0.7	−0.1	0.1	0	−0.1	−0.2	−0.7	0
Urban Hospitals Reclassified	451	0.8	0	0.1	0.1	1.9	0.4	0	0	0	−0.2	−1.1	−0.2
Urban Nonreclassified Hospitals, FY 2014	1990	0.8	0.1	0	0.2	−0.7	−0.1	0.1	0	0	−0.2	−0.8	0.2

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2014—Continued

	Number of hospitals [1] (1)	Proposed hospital rate update and documentation and coding adjustment [2] (2)	Proposed FY 2014 weights and DRG changes with application of recalibration budget neutrality [3] (3)	Proposed FY 2014 wage data with application of wage budget neutrality [4] (4)	Proposed FY 2014 DRG, rel. wts., wage index changes with wage and recalibration budget neutrality [5] (5)	Proposed FY 2014 MGCRB reclassifications [6] (6)	Proposed rural floor and imputed floor with application of national rural floor budget neutrality [7] (7)	Proposed application of the frontier wage index [8] (8)	Proposed FY 2014 outmigration adjustment [9] (9)	Expiration of MDH status [10] (10)	Proposed hospital readmissions reduction program [11] (11)	Proposed changes to Medicare DSH [12] (12)	All proposed FY 2014 changes [13] (13)
All Rural Hospitals Reclassified FY 2014	311	1.1	−0.3	−0.3	−0.5	2.7	−0.3	0	0	−0.8	−0.2	−1.6	−1.7
Rural Nonreclassified Hospitals FY 2014	552	1.2	−0.6	−0.2	−0.8	−0.2	−0.3	0.1	0.2	−1.7	−0.3	0.2	−2.2
All Section 401 Reclassified Hospitals	47	1.3	−0.4	−0.3	−0.6	−0.3	0	2.1	0	−2.4	−0.2	−0.2	−1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	61	1	−0.8	−0.7	−1.3	4.1	−0.4	0	0	−3.9	−0.2	0	−2.6
Specialty Hospitals													
Cardiac specialty Hospitals	15	0.8	1.1	0.3	1.5	−0.8	−0.2	0.7	0	0	−0.1	−0.1	1.4

[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 2012, and hospital cost report data are from reporting periods beginning in FY 2010 and FY 2009.

[2] This column displays the payment impact of the proposed hospital rate update, the documentation and coding adjustment and the adjustment to offset the costs of the proposed inpatient status policy including the 1.8 percent adjustment to the national standardized amount (the estimated 2.5 percent market basket update reduced by the proposed 0.4 percentage point for the multifactor productivity adjustment and the 0.3 percentage point reduction under the Affordable Care Act) and the 0.8 percent documentation and coding adjustment to the national standardized amount and the 0.2 percent adjustment for the policy proposal on admission and medical review criteria applied to the national standardized amount, hospital-specific rate and the Puerto Rico-specific amount.

[3] This column displays the payment impact of the proposed changes to the Version 31.0 GROUPER, the proposed changes to the relative weight methodology that uses 19 CCRs as opposed to 15 CCRs, and the proposed recalibration of the MS–DRG weights based on FY 2012 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.997583 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2010 cost report data and proposed changes to the labor-related share. This column displays the payment impact of the proposed 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 proposed wage budget neutrality factor is 0.999766

[5] This column displays the combined payment impact of the proposed changes in Columns 3 through 4 and the proposed 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 proposed cumulative wage and recalibration budget neutrality factor of 0.99783 is the product of the proposed wage budget neutrality factor and the proposed recalibration budget neutrality factor.

[6] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the proposed FY 2014 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2014. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.990971.

[7] This column displays the effects of the proposed rural floor and imputed floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor (which includes the proposed imputed floor) applied to the wage index is 0.990189.

[8] This column shows the 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.

[9] This column displays the impact 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 the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

[10] This column displays the impact of the expiration of MDH status for FY 2014, a non-budget neutral payment provision.

[11] This column displays the impact of the implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital's payment for excess readmissions.

[12] This column displays the impact of the implementation of section 3133 of the Affordable Care Act that reduces Medicare DSH payments by 75 percent and establishes an additional uncompensated care payment.

[13] This column shows the proposed changes in payments from FY 2013 to FY 2014. It reflects the impact of the proposed FY 2014 hospital update, the proposed adjustment for documentation and coding, and the proposed adjustment for the policy proposal on admission and medical review criteria. It also reflects proposed changes in hospitals' reclassification status in FY 2014 compared to FY 2013. It incorporates all of the proposed changes displayed in Columns 2, 5, 6, 7, 8, 9, 10, 11 and 12 (the proposed changes displayed in Columns 3 and 4 are included in Column 5). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

a. Effects of the Proposed Hospital Update, Documentation and Coding Adjustment and Adjustment for the Policy Proposal on Admission and Medical Review Criteria (Column 2)

As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 2.5 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.3 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2014 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. Finally, we are proposing a −0.2 percent adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A that is applied to the national standardized amount, the hospital-specific rate, and the Puerto Rico specific rate. As a result, we are proposing to make a 0.8 percent update to the national standardized amount.

This column also includes the proposed 1.6 percent update to the hospital-specific rates, which includes the proposed 1.8 percent for the hospital update and proposed −0.2 percent adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

Overall, hospitals would experience a 0.8 percent increase in payments primarily due to the effects of the hospital update and documentation and coding adjustment on the national standardized amount. Hospitals that are paid under the hospital-specific rate, namely SCHs, would experience a 1.6 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate would experience increases in payments of more than 0.8 percent.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 3)

Column 3 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are proposing to calculate a recalibration budget neutrality factor to account for the proposed changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2014 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2014, the MS–DRGs are calculated using the FY 2012 MedPAR data grouped to the Version 31.0 (FY 2014) MS–DRGs. In addition, for FY 2014, we are proposing to move from 15 departmental CCRs to 19 departmental CCRs to calculate the cost-based relative weights. The four additional CCRs of implantable devices, CT scan, MRI, and cardiac catheterization have generally increased the relative weight values for surgical MS–DRGs and decreased the relative weight values for medical MS–DRGs. The proposed methodology to calculate the relative weights and the proposed reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 3 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.997583 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases would experience increases in their payments due to the proposed changes to the relative weight methodology. Rural hospitals would experience a 0.5 percent decrease in payments because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents would experience an increase in payments by 0.2 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Proposed Wage Index Changes (Column 4)

Column 4 shows the impact of updated wage data and the proposed change to the labor-related share with the application of the proposed wage budget neutrality factor. Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2014 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2009 and before October 1, 2010. The estimated impact of the updated wage data and the proposed labor-related share on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the proposed percentage change in payments when going from a model using the FY 2013 wage index, based on FY 2009 wage data, the FY 2013 labor-related share of 68.8 percent and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2014 pre-reclassification wage index with the proposed labor-related share of 69.6 percent, also having a 100-percent occupational mix adjustment applied, based on FY 2010 wage data (while holding other payment parameters such as use of the Version 31.0 MS–DRG GROUPER constant). The proposed occupational mix adjustment is based on the 2010 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the proposed 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 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 2014, we are proposing to calculate the wage budget neutrality factor to ensure that payments under updated wage data and the proposed 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 proposed wage budget neutrality factor is 0.999766, and the overall proposed payment change is zero percent.

Column 4 shows the impacts of updating the wage data using FY 2010 cost reports. Overall, the new wage data and the proposed labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to a 0.0 percent change for all hospitals as shown in Column 4. Among the regions, the largest increase is in the urban Middle Atlantic region, which would experience 0.7 percent increase. The largest decline from updating the wage data and the proposed change in the labor-related share to 69.9 percent is seen in the rural West South Central region, rural East South Central, rural Puerto Rico and Urban East South Central (−0.5 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 2.0 percent compared to FY 2013. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 2.0 percent increase in average hourly wage. Of the 3,382 hospitals with wage data for both FYs 2013 and 2014, 1,626, or 48.1 percent, would experience an average hourly wage increase of 2.0 percent or more.

The following chart compares the shifts in proposed wage index values for hospitals due to changes in the average hourly wage data for FY 2014 relative to FY 2013. Among urban hospitals, none would experience an increase or decrease of more than 5 percent. Among rural hospitals, none would experience an increase or decrease of more than 5 percent. However, 918 rural hospitals would experience increases or decreases of less than 5 percent, while 2,464 urban hospitals would experience increases or decreases of less than 5 percent. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the proposed wage index before the proposed application of geographic reclassification, the proposed rural and imputed floors, the proposed out-migration adjustment, and other proposed wage index exceptions and adjustments. (We refer readers to sections III.G.2. through III.I. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the proposed ''post-reclassified wage index'' or ''payment wage index,'' the proposed wage index that includes all such exceptions and

adjustments (as reflected in Tables 2, 4A, 4B, 4C, and 4F of the Addendum to this proposed rule, which are available via the Internet on the CMS Web site) is used to adjust the proposed 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 proposed pre-reclassified wage index figures in the chart below may illustrate a somewhat larger or smaller change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the average hourly wage data for urban and rural hospitals.

Percentage change in proposed area wage index values	Number of hospitals	
	Urban	Rural
Increase more than 10 percent	0	0
Increase more than 5 percent and less than 10 percent	0	0
Increase or decrease less than 5 percent	2,464	918
Decrease more than 5 percent and less than 10 percent	0	0
Decrease more than 10 percent	0	0

d. Combined Effects of the Proposed MS–DRG and Wage Index Changes (Column 5)

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 proposed wage budget neutrality factor of 0.999766 and a proposed recalibration budget neutrality factor of 0.997583 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two proposed budget neutrality factors is the proposed cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.997350, or approximately −0.27 percent, which is applied to the proposed 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. In this proposed rule, we are estimating that the proposed changes in the MS–DRG relative weights and updated wage data with wage and budget neutrality applied would result in a 0.1 percent change in payments.

We estimate that the combined impact of the proposed changes to the relative weights and MS–DRGs and the updated wage data and the proposed change in the labor-related share with budget neutrality applied would result in 0.1 percent increase in payments for urban hospitals and 0.6 percent decrease in payments for rural hospitals primarily due to the proposed changes to the relative weights. Urban Middle Atlantic hospitals would experience a 0.7 percent increase in payments due to proposed increases in their wages compared to the national average, while the rural West South Central area would experience a 0.9 percent decrease in payments because of below average increases in wages and due to the proposed changes to the relative weights.

e. Effects of Proposed MGCRB Reclassifications (Column 6)

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 other bases than where they are geographically located). The proposed changes in Column 6 reflect the per case payment impact of moving from this baseline to a simulation incorporating the proposed MGCRB decisions for FY 2014 which affect hospitals' wage index area assignments.

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 proposing to apply an adjustment of 0.990971 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 proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.7 percent. By region, all the rural hospital categories, with the exception of one rural Puerto Rico hospital, would experience increases in payments due to MGCRB reclassifications. Rural hospitals in the New England region would experience a 3.2 percent increase in payments and rural hospitals in the Mountain region would experience a 0.2 percent increase in payments. Urban hospitals in New England and the Middle Atlantic would experience an increase in payments of 0.7 percent and 0.3 percent, respectively, largely due to reclassifications of hospitals in Connecticut and New Jersey.

Table 9A listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the reclassifications for FY 2014.

f. Effects of the Proposed Rural and Imputed Floor, Including Application of Proposed National Budget Neutrality (Column 7)

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, and 2013 IPPS/LTCH PPS final rules, and this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We apply a uniform budget neutrality adjustment to the wage index. In addition, 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. In the past, only urban hospitals in New Jersey had been receiving 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, we are proposing to extend the imputed rural floor, as calculated under the original methodology and the alternative methodology.

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 proposed FY 2014 rural floor budget neutrality factor to be applied to the wage index of 0.990189, which will reduce wage indexes by 0.98 percent.

Column 7 shows the projected impact of the proposed rural floor and proposed imputed floor with the proposed national rural floor budget neutrality factor applied to the proposed wage index. The column compares the proposed post-reclassification FY 2014 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2014 wage index of providers with the proposed rural floor and imputed floor adjustment. 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) would experience a decrease in payments due to the proposed budget

neutrality adjustment that is applied nationally to their wage index.

We estimate that 434 hospitals benefit from the proposed rural and imputed floors while the remaining 2,970 IPPS hospitals in our model have their proposed wage index reduced by the proposed rural floor budget neutrality adjustment of 0.990189 (or 0.98 percent). We project that, in aggregate, rural hospitals would experience a 0.3 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in other urban areas (populations of 1 million or fewer) would experience a 0.1 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 4.4 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts and Connecticut. All 60 urban providers in Massachusetts are expected to receive the proposed rural floor wage index value, including proposed rural floor budget neutrality, of 1.3108 increasing payments to Massachusetts by an estimated $169 million. During most past years, there have been no IPPS hospitals located in rural areas in Massachusetts. There was one urban IPPS hospital that was reclassified to rural Massachusetts (under section 1886(d)(8)(E) of the Act) which established the Massachusetts rural floor, but the wage index resulting from that hospital's data was not high enough for any urban hospital to benefit from the rural floor policy. However, beginning with the FY 2012 wage index, the rural floor for the State is established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. We estimate that Massachusetts hospitals would receive approximately a 5.6 percent increase in IPPS payments due to the application of the proposed rural floor. In addition, 27 out of 32 hospitals in Connecticut would benefit from the proposed rural floor, which would increase payments to the State by an estimated $75 million.

Urban Puerto Rico hospitals are expected to experience a 0.0 percent change in payments as a result of the application of a proposed Puerto Rico rural floor with the application of the proposed Puerto Rico rural floor budget neutrality adjustment. Urban Puerto Rico hospitals would receive a proposed rural floor as a result of a one IPPS hospital located in rural Puerto Rico setting the rural floor. We are proposing to apply a proposed rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.990877 or −0.9 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 nonrural floor urban Puerto Rico hospitals that have their wage indexes downwardly adjusted by the proposed rural floor budget neutrality adjustment. As a result, overall, urban Puerto Rico hospitals would experience a 0.0 percent change in payments due to the proposed application of the proposed rural floor with rural floor budget neutrality.

There are 35 hospitals in New Jersey that benefit from the extension of the proposed imputed floor and would receive the proposed imputed floor wage index value, including the proposed rural floor budget neutrality, of 1.1144, which we estimate would increase their payments by approximately $15 million. Urban Middle Atlantic hospitals would experience a 0.3 percent decrease in payments, which reflects the proposed increase in payments for New Jersey hospitals receiving the proposed imputed floor and a proposed decrease for other urban hospitals in the in the Middle Atlantic region. Four Rhode Island hospitals would benefit from the proposed imputed rural floor calculated under the alternative methodology and would receive an additional $3.5 million.

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 proposed 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 would receive the proposed rural floor or imputed floor wage index for FY 2014. Column 3 displays the percentage of total payments each State would receive or contribute to fund the proposed rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2014 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2013 wage index of providers with the proposed rural floor and imputed floor adjustment. Column 4 displays the estimated payment amount that each State would gain or lose due to the application of the proposed rural floor and imputed floor with national budget neutrality.

FY 2014 PROPOSED IPPS ESTIMATED PAYMENTS DUE TO PROPOSED RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals (1)	Number of hospitals receiving proposed rural floor or imputed floor (2)	Percent change in payments due to application of proposed rural floor and imputed floor with budget neutrality (3)	Difference (in millions) (4)
Alabama	93	3	−0.5	−$7.7
Alaska	6	4	3.3	4.7
Arizona	57	7	−0.4	−6.7
Arkansas	45	0	−0.5	−5.0
California	308	178	0.9	86.4
Colorado	46	7	0.1	1.5
Connecticut	32	27	4.9	75.0
Delaware	6	0	−0.6	−2.3
Washington, DC	7	0	−0.5	−2.5
Florida	168	5	−0.4	−29.6
Georgia	107	0	−0.5	−12.3
Hawaii	14	0	−0.4	−1.2
Idaho	14	0	−0.3	−1.0
Illinois	127	5	−0.6	−26.8
Indiana	89	4	−0.5	−12.9
Iowa	34	0	−0.5	−4.2
Kansas	55	0	−0.4	−3.7
Kentucky	65	1	−0.4	−7.6
Louisiana	99	4	−0.5	−6.5

FY 2014 PROPOSED IPPS ESTIMATED PAYMENTS DUE TO PROPOSED RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Number of hospitals receiving proposed rural floor or imputed floor (2)	Percent change in payments due to application of proposed rural floor and imputed floor with budget neutrality (3)	Difference (in millions) (4)
Maine	20	0	−0.5	−2.4
Massachusetts	61	60	5.6	169.1
Michigan	95	0	−0.5	−22.1
Minnesota	51	0	−0.5	−9.0
Mississippi	65	1	−0.5	−5.1
Missouri	77	0	−0.4	−10.7
Montana	12	4	−0.1	−0.4
Nebraska	23	0	−0.4	−2.5
Nevada	24	19	1.6	10.9
New Hampshire	13	9	0.8	3.6
New Jersey	64	35	0.4	14.8
New Mexico	25	0	−0.3	−1.5
New York	166	2	−0.6	−46.5
North Carolina	87	0	−0.4	−15.2
North Dakota	6	1	−0.3	−0.9
Ohio	137	3	−0.4	−17.7
Oklahoma	86	2	−0.4	−5.4
Oregon	33	0	−0.5	−4.5
Pennsylvania	157	6	−0.5	−21.8
Puerto Rico	52	13	0	0.0
Rhode Island	11	4	0.5	1.7
South Carolina	57	5	−0.3	−5.0
South Dakota	19	0	−0.3	−1.0
Tennessee	97	11	−0.3	−7.6
Texas	322	3	−0.5	−31.9
Utah	32	0	−0.4	−2.0
Vermont	6	0	−0.4	−0.8
Virginia	78	1	−0.4	−10.5
Washington	49	5	−0.2	−3.6
West Virginia	30	3	−0.3	−2.3
Wisconsin	66	2	−0.4	−7.3
Wyoming	11	0	−0.1	−0.2

g. Effects of the Proposed Application of the Frontier State Wage Index (Column 8)

Section 10324(a) of Affordable Care Act requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in ''frontier States.'' 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, four States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 46 hospitals located in those States will receive a frontier wage index of 1.0000. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 rural floor value of 1.0256 was greater and, therefore, was the State's minimum wage index for FY 2013. For FY 2014, its proposed post-reclassification wage index is also above 1.0000, hospitals located in Nevada would not experience a change in payment as a result of this provision. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $63 million or approximately 0.1 percent.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region would receive an increase in payments by 0.8 percent and 0.2 percent, respectively because many of the hospitals located in this region are frontier hospitals. Similarly, rural hospitals located in the Mountain region and rural hospitals in the West North Central region would experience an increase in payments by 0.4 percent and 0.3 percent, respectively.

h. Effects of the Proposed Wage Index Adjustment for Out-Migration (Column 9)

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. Overall, rural hospitals would experience a 0.1 percent increase in payments as a result of the proposed out-migration wage adjustment. Rural DSH providers with less than 100 beds would experience a 0.4 percent increase in payments. There are 210 providers that would receive the proposed out-migration wage adjustment in FY 2014. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the proposed out-migration increase to be approximately $17 million.

i. Effects of the Expiration of MDH Special Payment Status (Column 10)

Column 10 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. MDH status had previously expired for FY 2013 under section 3124 of the Affordable Care Act, but was extended for an additional year through FY 2013 under section 606 of the ATRA. Hospitals that qualified to be MDHs receive the higher of

payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a 0.1 percent decrease in payments overall. There are currently 192 MDHs, of which 134 are estimated to be paid under the blended payment of the Federal standardized amount and hospital-specific rate for FY 2013. Because those 134 MDHs will no longer receive the blended payment and will be paid only under the Federal standardized amount in FY 2014, it is estimated that those hospitals will experience an overall decrease in payments of approximately $127 million.

MDHs were generally rural hospitals, so the expiration of the MDH program will result in an overall decrease in payments to rural hospitals of 1.2 percent. Rural New England hospitals can expect a decrease in payments of 3.9 percent because 8 out of the 23 rural New England hospitals are MDHs that will lose this special payment status under the expiration of the program at the end of FY 2013. MDHs can expect a decrease in payments of 9.9 percent.

j. Effects of the Proposed Reductions Under the Hospital Readmissions Reduction Program (Column 11)

Column 11 shows our estimates of the effects of the proposed policies for reductions in payments under the Hospital Readmissions Reduction Program, which was established under section 3025 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions, which is based on a hospital's risk-adjusted readmission rate during a 3-year period for three applicable conditions: Acute Myocardial Infarction, Heart Failure, and Pneumonia. 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 statute as 0.98 (or a 2.0 percent reduction) for FY 2014. A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section V.G. of the preamble of this proposed 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 proposed rule, we estimate that 2,173 hospitals will have their base operating DRG payments reduced by their hospital-specific proposed readmissions adjustment, resulting in a 0.2 percent decrease, or approximately $175 million, in payments to hospitals overall for FY 2014 relative to no provision.

Urban hospitals in the Middle Atlantic, rural hospitals in the East South Central region, West South Central region, rural DSH hospitals and hospitals with Medicare utilization of over 65 percent would experience the highest decreases of 0.4 percent among the different hospital categories. Rural New England hospitals would experience the no change in payments. Puerto Rico hospitals show a 0 percent change in payments because they are exempt from the provision.

k. Effects of the Proposed Changes to Medicare DSH Payments (Column 12)

Column 12 shows the proposed effects of the implementation of adjustments to Medicare DSH payments made under section 3133 of the Affordable Care Act. Under section 3133, hospitals that are eligible to 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. The remainder, 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 additional statutory adjustments, will become available to make additional payments to each hospital that qualifies for Medicare DSH payments. Each Medicare DSH hospital will receive an additional payment based on its estimated share of the total amount of uncompensated care for all Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

We are proposing that the amount to be distributed on the basis of uncompensated care, which is 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments (that is, Factor 1), is adjusted to 88.8 percent of that amount for changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments (that is, Factor 1 multiplied by Factor 2). As a result, we project that the reduction of Medicare DSH payments, together with the introduction of the new uncompensated care payment, will reduce payments overall by 0.9 percent as compared to Medicare DSH payments prior to the implementation of section 3133 of the Affordable Care Act. The proposed uncompensated care payment has redistributive effects based on a disproportionate share hospital's low income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to all disproportionate share hospitals Medicaid patient days and Medicare SSI patient days, and the payment amount is not tied to a hospital's discharges. Urban hospitals located in the Pacific would experience the largest decreases in payments of 3.2 percent, as these hospitals have lower uncompensated care relative to other hospital categories. Hospitals with low Medicare utilization with Medicare days that are less than 25 percent of total inpatient days would experience a 4.4 percent increase in payment.

l. Effects of All Proposed FY 2014 Changes (Column 13)

Column 13 shows our estimate of the changes in payments per discharge from FY 2013 and FY 2014, resulting from all proposed changes reflected in this proposed rule for FY 2014. It includes combined effects of the previous columns in the table.

The proposed average decrease in payments under the IPPS for all hospitals is approximately 0.1 percent for FY 2014 relative to FY 2013. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2014 documentation and coding 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 proposed annual hospital update of 1.8 percent to the national standardized amount. This annual hospital update includes the proposed 2.5 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.3 percentage point reduction under section 3401 of the Affordable Care Act. Finally, it includes the proposed −0.2 percent adjustment of the national standardized amount, the hospital-specific payment rate, and the Puerto Rico-specific rate to offset the costs of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A. As described in Column 2, the proposed annual hospital update, combined with the proposed documentation and coding adjustment and the adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A, would result in a 0.8 percent increase in payments in FY 2014 relative to FY 2013. Column 5 shows an increase in payments by 0.1 percent due to the effects of the cumulative DRG and wage budget neutrality. Column 8 describes an estimated 0.1 percent increase in payments due to the proposed frontier State wage index. Column 10 describes the estimated 0.1 percent decrease in payments due to the expiration of the MDH status under section 606 of the ATRA. Column 11 shows the estimated 0.2 percent decrease in payments due to the proposed reductions in payments under the Hospital Readmissions Reduction Program, which reduce a hospital's base operating DRG payments by a readmission adjustment factor based on a hospital's performance on readmissions for specified conditions. Column 12 shows the estimated 0.9 percent decrease in Medicare DSH payments due to the changes made under section 3133 of the Affordable Care Act, which reduces Medicare DSH payments by 75 percent and redistributes the remainder, 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, to each hospital that qualifies for Medicare DSH payments as an uncompensated care payment based on the hospital's relative share of the total amount of uncompensated care. The impact of moving from our estimate of FY 2013 outlier payments, 5.2 percent, to the estimate of FY 2014 outlier payments, 5.1 percent, would result in a decrease of 0.1 percent in FY 2014 payments relative to FY 2013. 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 13 may not equal the sum of the estimated percentage changes described above.

Overall payments to hospitals paid under the IPPS are estimated to decrease by 0.1

percent for FY 2014. The proposed payment decrease among the hospital categories is largely attributed to the reduction in Medicare DSH payment adjustments and the redistribution of a portion of the Medicare DSH payments as an additional payment for a hospital's relative uncompensated care amount. Hospitals in urban areas would experience a 0.1 percent increase in payments per discharge in FY 2014 compared to FY 2013. Hospital payments per discharge in rural areas are estimated to decrease by −1.9 percent in FY 2014 as compared to FY 2013 largely due to the expiration of MDH status and reductions to Medicare DSH payments.

Among urban census divisions, the Urban Pacific hospitals would experience an estimated 1.5 percent decrease in payments, more than the national average, because many of the urban providers in this region would see reductions to their Medicare DSH payments. Urban hospitals in the Middle Atlantic would experience a 1.6 percent increase in payments.

Among the rural regions, the hospitals in the East South Central region would experience the estimated decreases in payments of 3.5 percent, due to the expiration of MDH status and reductions to Medicare DSH payments. Rural hospitals in the Mountain region are estimated to experience no change in payments.

Among special categories of hospitals, former MDHs would receive an estimated payment decrease of 8.5 percent due to the expiration of the MDH special payment status. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs are estimated to experience a payment decrease of 0.5 percent due to the proposed changes to the relative weights methodology and minor reductions under the rural floor budget neutrality and changes to Medicare DSH.

Rural hospitals reclassified for FY 2014 would receive an estimated 1.7 percent payment decrease. Rural hospitals that are not reclassifying are estimated to receive a payment decrease of 2.2 percent due to lower wage data, the application of the proposed rural floor budget neutrality and expiration of MDH status. Urban reclassified hospitals would experience an estimated payment decrease of 0.2 percent due to decreases in payments under the Medicare DSH changes. Urban nonreclassified hospitals would experience an estimated payment increase of 0.2 percent.

Cardiac hospitals are expected to experience a payment increase of 1.4 percent in FY 2014 relative to FY 2013 primarily due to the proposed changes in the relative weights and the proposed application of the frontier State wage index.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2014 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 2013 with the average payments per discharge for FY 2014, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 13 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2014 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments Per Discharge]

	Number of hospitals	Proposed average FY 2013 payment per discharge	Proposed average FY 2014 payment per discharge	All proposed FY 2014 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,404	10,891	10,880	−0.1
By Geographic Location:				
Urban hospitals	2,481	11,305	11,315	0.1
Large urban areas	1,367	11,978	12,033	0.5
Other urban areas	1,114	10,488	10,443	−0.4
Rural hospitals	923	8,110	7,957	−1.9
Bed Size (Urban):				
0–99 beds	622	8,742	8,825	0.9
100–199 beds	762	9,538	9,488	−0.5
200–299 beds	464	10,234	10,223	−0.1
300–499 beds	418	11,637	11,653	0.1
500 or more beds	215	13,815	13,870	0.4
Bed Size (Rural):				
0–49 beds	339	6,537	6,379	−2.4
50–99 beds	328	7,551	7,304	−3.3
100–149 beds	151	7,859	7,772	−1.1
150–199 beds	59	8,970	8,870	−1.1
200 or more beds	46	9,829	9,710	−1.2
Urban by Region:				
New England	120	12,354	12,376	0.2
Middle Atlantic	318	12,367	12,560	1.6
South Atlantic	375	10,289	10,288	0
East North Central	395	10,498	10,475	−0.2
East South Central	149	9,895	9,865	−0.3
West North Central	165	11,069	11,051	−0.2
West South Central	371	10,371	10,358	−0.1
Mountain	156	11,613	11,751	1.2
Pacific	381	14,431	14,208	−1.5
Puerto Rico	51	5,505	7,469	35.7
Rural by Region:				
New England	23	10,960	10,642	−2.9
Middle Atlantic	69	8,618	8,519	−1.2
South Atlantic	165	7,771	7,628	−1.8
East North Central	119	8,310	8,180	−1.6
East South Central	171	7,452	7,193	−3.5
West North Central	100	8,610	8,574	−0.4

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2014 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments Per Discharge]

	Number of hospitals	Proposed average FY 2013 payment per discharge	Proposed average FY 2014 payment per discharge	All proposed FY 2014 changes
	(1)	(2)	(3)	(4)
West South Central	181	7,047	6,858	−2.7
Mountain	65	9,061	9,065	0
Pacific	29	10,996	10,961	−0.3
Puerto Rico	1	2,799	2,927	4.6
By Payment Classification:				
Urban hospitals	2,495	11,295	11,305	0.1
Large urban areas	1,377	11,967	12,021	0.5
Other urban areas	1,118	10,468	10,424	−0.4
Rural areas	909	8,241	8,087	−1.9
Teaching Status:				
Nonteaching	2,378	9,128	9,057	−0.8
Fewer than 100 residents	782	10,676	10,670	−0.1
100 or more residents	244	15,902	16,036	0.8
Urban DSH:				
Non-DSH	706	9,423	9,445	0.2
100 or more beds	1,562	11,763	11,764	0
Less than 100 beds	330	8,061	8,157	1.2
Rural DSH:				
SCH	260	8,158	8,052	−1.3
RRC	223	9,048	8,902	−1.6
100 or more beds	29	7,100	7,117	0.2
Less than 100 beds	294	6,414	6,187	−3.6
Urban teaching and DSH:				
Both teaching and DSH	826	12,856	12,902	0.4
Teaching and no DSH	135	10,466	10,543	0.7
No teaching and DSH	1,066	9,658	9,595	−0.6
No teaching and no DSH	468	9,036	9,062	0.3
Special Hospital Types:				
RRC	207	9,347	9,214	−1.4
SCH	329	8,825	8,782	−0.5
Former MDH	192	6,817	6,236	−8.5
SCH and RRC	124	9,924	9,918	−0.1
Former MDH and RRC	11	8,586	7,520	−12.4
Type of Ownership:				
Voluntary	1,944	11,020	11,005	−0.1
Proprietary	895	9,759	9,670	−0.9
Government	546	11,776	11,902	1.1
Medicare Utilization as a Percent of Inpatient Days:				
0–25	368	14,920	15,810	6
25–50	1,807	11,442	11,378	−0.6
50–65	967	8,932	8,861	−0.8
Over 65	171	7,914	7,767	−1.9
FY 2014 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	762	10,510	10,454	−0.5
Non-Reclassified Hospitals	2,642	11,022	11,026	0
Urban Hospitals Reclassified	451	11,271	11,252	−0.2
Urban Nonreclassified Hospitals, FY 2014:	1,990	11,336	11,356	0.2
All Rural Hospitals Reclassified FY 2014:	311	8,609	8,460	−1.7
Rural Nonreclassified Hospitals FY 2014:	552	7,439	7,275	−2.2
All Section 401 Reclassified Hospitals:	47	9,523	9,382	−1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	61	7,754	7,549	−2.6
Specialty Hospitals:				
Cardiac specialty Hospitals	15	11,720	11,888	1.4

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed above that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed below.

1. Effects of Proposed Policy on MS–DRGs for Preventable HACs, Including Infections

In section II.F. of the preamble of this proposed 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 proposed 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.

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 2014	$26
FY 2015	28
FY 2016	30
FY 2017	33
FY 2018	36

In section V.I. of the preamble of this proposed rule, we are proposing to implement the HAC Reduction Program. We refer readers to section I.H.6. of this Appendix A for a discussion of the impact of this proposed implementation.

2. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this proposed rule, we discuss the five applications for add-on payments for new medical services and technologies for FY 2014, as well as the status of the four new technologies that were approved to receive new technology add-on payments in FY 2013. As explained in that section, add-on payments for new technology 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 proposed rule, we have yet to determine whether any of the five applications we received for consideration for new technology add-on payments for FY 2014 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these five applications for any potential new technology add-on payments for FY 2014. We note that if any of the five applications are found to be eligible for new technology add-on payments for FY 2014, in the FY 2014 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2014 in that final rule.

In the preamble to this proposed rule, we are proposing to continue making new technology add-on payments in FY 2014 for three of the four new technologies (Voraxaze®, Dificid™ and the Zenith® F. Graft) that were approved to receive new technology add-on payments in FY 2013. 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 2014 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. For Voraxaze®, based on the applicant's estimate from FY 2013, we currently estimate that new technology add-on payments for Voraxaze® will increase overall FY 2014 payments by $6,300,000. For Dificid™, based on the applicant's estimate from FY 2013, we currently estimate that new technology add-on payments for Dificid™ will increase overall FY 2014 payments by $34,839,784. For the Zenith® F. Graft, based on the applicant's estimate from FY 2013, we currently estimate that new technology add-on payments for the Zenith® F. Graft will increase overall FY 2014 payments by $4,085,750.

3. Effects of the Proposed Payment Adjustment for Low-Volume Hospitals for FY 2014

In section V.C. of the preamble to this proposed rule, we discuss the provisions of the ATRA (Pub. L. 112–240) which extended for an additional year, through FY 2013, the temporary changes to the low-volume hospital definition and methodology for determining the payment adjustment made by the Affordable Care Act for FYs 2011 and 2012. In accordance with section 1886(d)(12) of the Act, beginning with FY 2014, the low-volume hospital definition and payment adjustment methodology revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, effective for FY 2014 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Based on FY 2012 claims data (December 2012 update of the MedPAR file), we estimate that approximately 600 hospitals qualify as a low-volume hospital in FY 2013, and with the statutory changes to the low-volume hospital payment adjustment for FY 2014, we estimate only approximately 6 hospitals will continue to qualify as a low-volume hospital in FY 2014. We project that the expiration of the temporary changes to the low-volume hospital definition and payment adjustment methodology made by the Affordable Care Act and extended by the ATRA will result in a decrease in payments of approximately $288 million in FY 2014 as compared to the payments these hospitals would have otherwise received in FY 2014 in the absence of the statutory changes to the low-volume hospital payment adjustment for FY 2014. This estimate accounts for our projection of the 6 IPPS low-volume hospitals remaining in FY 2014 that will continue to receive a low-volume hospital payment adjustment of an additional 25 percent.

4. Effects of Extension of the MDH Program Through FY 2013

In section V.F. of the preamble of this proposed rule, we briefly discuss the statutory extension of the MDH program through FY 2013 made by section 606 of the ATRA. We refer readers to a March 7, 2013 notice that we published in the **Federal Register** to announce the extension of the MDH program for FY 2013 in accordance with this ATRA provision, where we also stated the impact on Medicare expenditures of the statutory extension (78 FR 14689).

5. Effects of Changes Under the FY 2014 Hospital Value-Based Purchasing (VBP) Program

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals that meet performance standards during the performance period for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2014 through a reduction to the FY 2014 base operating MS–DRG payment for each discharge of 1.25 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent. We are required to ensure that the total amount available for value-based incentive payments is equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

We finalized numerous policies related to the FY 2014 Hospital VBP Program in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614), including an additional measure in the Clinical Process of Care domain, minimum numbers of cases and measures for the Outcome domain, performance and baseline periods for FY 2014 measures, performance standards, domain weighting, and requirements for the review and corrections processes. We also refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26495 through 26511) where we finalized three 30-day mortality measures, to be placed in the new Outcome domain for the FY 2014 Hospital VBP Program.

In section V.H. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2014 Hospital VBP Program, which, in accordance with section 1886(o)(7)(C)(ii) of the Act, will be 1.25 percent of base operating DRG payments, or a total of approximately $1.1 billion. This estimated available pool for FY 2014 is based on the historical pool of hospitals that were eligible to participate in the FY 2013 Hospital VBP Program and the payment information from the December 2012 update to the FY 2012 MedPAR file. We intend to provide an update to this estimate, which will be based on the March 2013 update to the FY 2012 MedPAR file, in the FY 2014 IPPS/LTCH PPS final rule.

The estimated impacts of the FY 2014 Hospital VBP Program by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2013 Hospital VBP Program 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 2013 update to the FY 2012 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available on the CMS Web site). The impact analysis shows that, for the FY 2014 Hospital VBP Program, the number of hospitals that would receive an increase in base operating DRG payment amount is slightly higher than the number of hospitals that would receive a decrease. Approximately 44 percent of hospitals would have a change in base operating DRG payment amount that is between −0.2 percent and +0.2 percent. Urban hospitals in the West South Central region and rural hospitals in the East North Central region would have the highest average increase in base operating DRG payment amount while both urban and rural hospitals in the Middle Atlantic and Pacific would receive an average decrease in base operating DRG payment amount. As the percent of disproportionate share (DSH) payments increases, we would see a decrease in base operating DRG payment amounts, while as the Medicare utilization (MCR) percent increases, we would see an increase in base operating DRG payment amount. Nonteaching hospitals would have an average positive adjustment to the base operating DRG payment amount, and teaching hospitals would have an average decrease in base operating DRG payment amount.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2014 HOSPITAL VBP PROGRAM

	Number of hospitals	Case weighted average (in percent)
BY GEOGRAPHIC LOCATION:		
All Hospitals	2,984	0.000
Large Urban	1,226	−0.003
Other Urban	1,015	0.002
Rural Area	740	0.005
Urban hospitals	2,241	−0.001
0–99 beds	465	0.149
100–199 beds	717	0.014
200–299 beds	435	0.015
300–499 beds	421	−0.010
500 or more beds	203	−0.048
Rural hospitals	740	0.005
0–49 beds	162	0.049
50–99 beds	324	−0.029
100–149 beds	150	0.027
150–199 beds	57	−0.004
200 or more beds	47	0.021
BY REGION:		
Urban By Region	2,241	−0.001
New England	113	−0.020
Middle Atlantic	295	−0.066
South Atlantic	356	0.049
East North Central	373	0.024
East South Central	129	0.019
West North Central	155	0.002
West South Central	314	0.042
Mountain	155	−0.013
Pacific	351	−0.078
Rural By Region	740	0.005
New England	21	−0.103
Middle Atlantic	64	−0.115
South Atlantic	143	0.021
East North Central	117	0.104
East South Central	114	0.064
West North Central	85	−0.032
West South Central	114	−0.053
Mountain	54	−0.017
Pacific	28	−0.100
Puerto Rico		
By MCR Percent:		
0–25	288	−0.082

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2014 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Case weighted average (in percent)
25–50	1,715	−0.003
50–65	853	0.019
Over 65	79	0.081
BY DSH Percent:		
0–25	1,429	0.033
25–50	1,257	−0.010
50–65	157	−0.120
Over 65	138	−0.187
BY TEACHING STATUS:		
Teaching	971	−0.031
Non-Teaching	2,010	0.033

We intend to provide an updated impact analysis in the FY 2014 IPPS/LTCH PPS final rule. However, actual FY 2014 Hospital VBP Program TPSs will not be reviewed and corrected by hospitals until after the FY 2014 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2013 Hospital VBP Program will be used for that updated impact analysis. The updated impact analysis for the final rule will reflect estimated annual base operating DRG payment amount changes based on the December 2012 update to the FY 2012 MedPAR file.

6. Effects of Proposed Implementation of the HAC Reduction Program

In section V.I. of the preamble of this proposed rule, we are proposing measures, scoring, and risk adjustment methodology to implement the FY 2015 payment reduction under the HAC Reduction Program. Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an adjustment to hospital payments for HACs, or a HAC Reduction program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce HACs, effective for discharges beginning on October 1, 2014 and for subsequent program years.

We note that there is no payment impact for FY 2014. For FY 2015, we are presenting the overall impact of the HAC Reduction Program provision along with other IPPS payment provision impacts in section I.G. of this Appendix A. The tables and analyses that we are presenting below show the distributional effect of the measures and scoring system for this program included in this proposed rule.

The four tables below show the following data distribution:

- The first table presents data on hospitals in the top (that is, worst performing) quartile for the Domain 1-Proposed Approach and the Domain 1-Alternative Approach scores, with hospital scores segregated by hospital types.
- The second table presents data on hospitals in the top (that is, worst performing) quartile for Domain 2 scores, with hospital scores segregated by hospital types.
- The third table presents data on hospitals in top (that is, worst performing) quartile for Total HAC Scores for the Domain 1—Proposed Approach and the Domain 1—Alternative Approach, with hospital scores segregated by hospital types.
- The fourth table presents data on (1) hospitals that have complete data for Domain 1 (that is, data for at least three measures for the Domain 1—Proposed Approach or on hospitals that have enough data to calculate PSI 90 for the Domain 1—Alternative Approach), with hospital scores segregated by hospital type; and (2) hospitals that have complete data for Domain 2 (that is, at least one measure for Domain 2), with hospital scores segregated by hospital types.

The data for these data tables are derived from 3,445 IPPS hospitals (minus CAHs) for the time period of July 1, 2009 to June 30, 2011. The data source for Domain 1 is the Standard Analytic File (SAF) claims data, and the data source for Domain 2 is the chart-abstracted data on CDC's National Healthcare Safety Network (NHSN). The data used to determine teaching status and for-profit/not-for-profit/government-owned status in the fourth table is derived from American Hospital Association (AHA) 2010 Annual Survey of Hospital data, while the data used to determine DSH status in the fourth table is derived from the CMS FY 2013 IPPS Impact File. Maryland hospitals were excluded from the data in the fourth table because Maryland hospitals were not required to submit POA data in their claims and, therefore, no AHRQ measures could be calculated. Finally, the data source for the Region/Division categories of all four tables is the Citation of Region/Division data available on the Web site at *https://www.census.gov/geo/www/us_regdiv.pdf,* and the data source for the Urban/Rural categories for all four tables is the Urban/Rural data from the U.S. department of Agriculture's Economic Research Service, which is available on the Web site at: *http://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx.*

HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR DOMAIN 1—PROPOSED APPROACH SCORE AND DOMAIN 1—ALTERNATIVE APPROACH SCORE

Hospital category	In top quartile Domain 1—proposed approach score			Not in top quartile Domain 1—proposed approach score			Domain 1—proposed approach totals	In Top quartile Domain 1—alternative approach score			Not in top quartile Domain 1—alternative approach score			Domain 1—alternative approach totals
	Number of hospitals	Percent of total	Percent of hospital type	Number of hospitals	Percent of total	Percent of hospital type		Number of hospitals	Percent of total	Percent of hospital type	Number of hospitals	Percent of total	Percent of hospital type	
Teaching status														
Teaching	149	19.2	55.2	121	4.6	44.8	270	154	17.9	57	116	4.5	43	270
Non-teaching	614	79	20.2	2,423	91.2	79.8	3,037	690	80.4	22.7	2,347	91.1	77.3	3,037
No information	14	1.8	10.9	114	4.3	89.1	128	14	1.6	10.9	114	4.4	89.1	128
Total	777	.....	22.6	2,658	.....	.....	3,435	858	.....	25	2,577	.....	.....	3,435
DSH Status														
DSH	639	82.2	24.2	2,002	75.3	75.8	2,641	703	81.9	26.6	1,938	75.2	73.4	2,641
Non-DSH	130	16.7	17.6	610	22.9	82.4	740	147	17.1	19.9	593	23	80.1	740
No information	8	1	14.8	46	1.7	85.2	54	8	0.9	14.8	46	1.8	85.2	54
Total	777	.....	22.6	2,658	.....	.....	3,435	858	.....	25.1	2,577	.....	.....	3,435
Bed Size														
Under 50	60	7.7	9.1	596	22.4	90.9	656	73	8.5	11.1	583	22.6	88.9	656
50–99	143	18.4	21.1	535	20.1	78.9	678	159	18.5	23.5	519	20.1	76.5	678
100–199	190	24.5	21.5	694	26.1	78.5	884	224	26.1	25.3	660	25.6	74.7	884
200–299	118	15.2	23.6	381	14.3	76.4	499	135	15.7	27.1	364	14.1	72.9	499
300–399	90	11.6	34.2	173	6.5	65.8	263	90	10.5	34.2	173	6.7	65.8	263
400–499	57	7.3	46	67	2.5	54	124	62	7.2	50	62	2.4	50	124
500 or more	105	13.5	51.7	98	3.7	48.3	203	101	11.8	49.8	102	4	50.2	203
No information	14	1.8	10.9	114	4.3	89.1	128	14	1.6	10.9	114	4.4	89.1	128
Total	777	.....	22.6	2,658	.....	.....	3,435	858	.....	25	2,577	.....	.....	3,435
Ownership														
For-profit	133	17.1	17.6	621	23.4	82.4	754	157	18.3	20.8	597	23.2	79.2	754
Government	115	14.8	20.6	443	16.7	79.4	558	135	15.7	24.2	423	16.4	75.8	558
Non-profit	515	66.3	25.8	1,480	55.7	74.2	1,995	552	64.3	27.7	1,443	56	72.3	1,995
No infomation	14	1.8	10.9	114	4.3	89.1	128	14	1.6	10.9	114	4.4	89.1	128
Total	777	.....	22.6	2,658	.....	858	3,435	858	.....	25	2,577	.....	.....	3,435
Region/Division														
Northeast	151	19.4	28.3	382	14.4	71.7	533	137	16	25.7	396	15.4	74.3	533
New England	37	4.8	25.9	106	4	74.1	143	37	4.3	25.9	106	4.1	74.1	143
Mid-Atlantic	114	14.7	29.2	276	10.4	70.8	390	100	11.7	25.6	290	11.3	74.4	390
Midwest	188	24.2	23.5	613	23.1	76.5	801	201	23.4	25.1	600	23.3	74.9	801
East North Central	124	16	23.6	402	15.1	76.4	526	137	16	26	389	15.1	74	526
West North Central	64	8.2	23.3	211	7.9	76.7	275	64	7.5	23.3	211	8.2	76.7	275
South	278	35.8	19.2	1,168	43.9	80.8	1,446	309	36	21.4	1,137	44.1	78.6	1,446
South Atlantic	117	15.16	21.2	434	16.3	78.8	551	140	16.3	25.4	411	15.9	74.6	551
East South Central	59	7.6	17.9	270	10.2	82.1	329	61	7.1	18.5	268	10.4	81.5	329
West South Central	102	13.1	18	464	17.5	82	566	108	12.6	19.1	458	17.8	80.9	566
West	160	20.6	24.4	495	18.6	75.6	655	211	24.6	32.2	444	17.2	67.8	655
Mountain	58	7.5	24.2	182	6.8	75.8	240	82	9.6	34.2	158	6.1	65.8	240
Pacific	102	13.1	24.6	313	11.8	75.4	415	129	15	31.1	286	11.1	68.9	415
Total	777	.....	22.6	2,658	.....	.....	3,435	858	.....	.....	2,577	.....	.....	3,435
Urban/Rural														
Urban	601	77.3	24.4	1,860	70	75.6	2,461	689	80.3	28	1,772	68.8	72	2,461
Rural	176	22.7	18.3	788	29.6	81.7	964	168	19.7	17.4	796	30.9	82.6	964
No information	0	0	0	10	0.4	100	10	1	0.1	10	9	0.3	90	10
Total	777	.....	22.6	2,658	3,435	3,435	3,435	3,435	3,435	3,435	3,435	3,435	3,435	3,435

The first table above shows the characteristics of the worst performing hospitals for the Domain 1—Proposed Approach score and for the Domain 1—Alternative Approach score. In the first table, of the hospitals in the top quartile for Domain 1—Proposed Approach, 19.2 percent were teaching hospitals, 79.0 percent were nonteaching hospitals, 82.2 percent were disportionate share hospitals, 16.7 percent were nondisportionate share hospitals, 50.6 percent were hospitals with a bed size of 199 or smaller, and 66.3 percent were nonprofit. In the first table, of the hospitals in the top quartile for Domain 1—Alternative Approach, 17.9 percent were teaching hospitals, 80.4 percent were nonteaching hospitals, 81.9 percent were disproportionate share hospitals, 17.1 percent were nondisproportionate share hospitals, 53.1 percent were hospitals with a bed size of 199 or smaller, and 64.3 percent were nonprofit. Altogether, 3,435 hospitals had complete data for the Domain 1—Proposed Approach score and the Domain 1—Alternative Approach score. Among these hospitals, the majority (3,037 for both approaches) were nonteaching hospitals, with the majority of these nonteaching hospitals (2,423, or 79.8 percent, for the proposed approach, and 2,347, or 77.3 percent, for the alternative approach) not in the top quartile score. A minority of the hospitals (270 for both approaches) were teaching hospitals; less than half of these hospitals (121, or 44.8 percent, for the proposed approach, and 116, or 43.0 percent, for the alternative approach) were not in the top quartile score. Of those hospitals that were not in the top quartile score, the nonteaching hospitals were the majority (2,423, or 91.2 percent, for the proposed approach, and 2,347, or 91.1 percent, for the alternative approach). Most of these hospitals were DSHs (2,641 for both approaches), with a minority being non-DSHs (40 for both approaches). The majority of the DSHs (2,002, or 75.8 percent, for the proposed approach, and 1,938, or 73.4 percent, for the alternative approach) were not in the top quartile score. Slightly less than a quarter of the DSHs (639, or 24.2 percent, for the proposed approach, and 703, or 26.6 percent, for the alternative approach) were in the top quartile (that is, worst performing) score.

In terms of bed size for both the Domain 1—Proposed Approach and the Domain 1—Alternative Approach, the majority of hospitals had less than 300 beds and the majority of these were not in the top quartile score. The majority (884 for both approaches) of hospitals with less than 300 beds were in the 100–199 bed size range. Of those 884 hospitals, the majority (694, or 78.5 percent, for the proposed approach, and 600, or 74.7 percent for the alternative approach) were not in the top quartile score. The minority of hospitals for both approaches had greater than 300 beds. The hospitals with 300–399 bed size range (263 for both approaches) had a majority of hospitals (173, or 65.8 percent, for both approaches) not in the top quartile score. For the Domain 1—Proposed Approach, the hospitals with 400–499 bed size range (124) also had a majority of hospitals (67, or 54.0 percent) not in the top quartile score; however, hospitals with a 500 or more bed size range (203) had a slight majority (105, or 51.7 percent) in the top quartile (that is, worst performing) score. For the Domain 1—Alternative Approach, hospitals with 400–499 bed size range (124) had an equal number of hospitals (62, or 50 percent) in the top quartile (that is, worst performing) score as not in the top quartile score, while hospitals with a 500 or more bed size range had an extremely slight majority (102 or 50.2 percent) not in the top quartile score compared to hospitals in the top quartile (that is, worst performing) score (101, or 49.8 percent).

In terms of ownership, for both the Domain 1—Proposed Approach and the Domain 1—Alternative Approach, more than half of the total of these 3,435 hospitals were nonprofit (1,995). Of these nonprofit hospitals, the majority (1,480, or 74.2 percent for the proposed approach, and 1,443, or 72.3 percent for the alternative approach) were not in top quartile score, while for-profit hospitals (754 for both approaches) also had a majority (621, or 82.4 percent, for the proposed approach, and 597, or 79.2 percent, for the alternative approach) not in top quartile score.

In terms of region/division for both the Domain 1—Proposed Approach and the domain 1—Alternative Approach, of the total 3,435 hospitals, the Northeast region had a total of 533 hospitals with a minority (143) in New England region and a majority (390) in Mid-Atlantic region. The Midwest region had a total of 801 hospitals, with a majority (526) in the East North Central region and the minority (275) in the West North Central region. The South region had the majority of hospitals by a region (1,446), with the South Atlantic region (551) and the West South Central region (566) having similar numbers of hospitals and the East South Central region having the minority of hospitals (329) of the South region. The West region had a total of 655 hospitals, with a majority in the Pacific region (415) and the minority in the Mountain region (240). The South region had the largest number of hospitals (278, or 35.8 percent for the proposed approach, and 309, or 36.0 percent, for the alternative approach) in the top quartile score. For the Domain 1—Proposed Approach, the Northeast New England region had the lowest number of hospitals (37, or 4.8 percent) in the top quartile score, with the Mountain region (58, or 7.5 percent) and the East South Central region (59, or 7.6 percent) having the next lowest number of hospitals in the top quartile score. For the Domain 1—Alternative Approach, the New England region had the lowest number of hospitals (37, or 4.3 percent) in the top quartile score, with the East South Central region (61, or 7.1 percent) and the West North Central region (64, or 7.5 percent) having the next lowest number of hospitals in the top quartile score. For both approaches, the South region had the largest number (1,168, or 43.9 for the proposed approach, and 1,137, or 44.1 percent for the alternative approach) not in the top quartile score, with the New England region having the lowest number of hospitals (106, or 4.0 for the proposed alternative, and 106, or 4.1 percent for the alternative approach) not in the top quartile score. The Mountain region (182, or 6.8 percent for the proposed approach, and 158, or 6.1 percent for the alternative approach) and the West North Central region (211, or 7.9 percent in the proposed approach, and 211, or 8.2 percent for the alternative approach) having the next lowest amount of hospitals not in the top quartile score.

In terms of urban/rural location of the total 3,435 hospitals, for the Domain 1—Proposed approach and the Domain 1—Alternative Approach, the majority of hospitals (2,461) were urban, and a minority of hospitals (964) being rural. Of the total urban hospitals (2,461), for the Domain 1—Proposed approach, there were 1,860 urban hospitals (75.6 percent) not in top quartile score; the 1,860 urban hospitals also were the majority (70.0 percent) of hospitals not in top quartile score. There were 601 urban hospitals (24.4 percent) in the top quartile score for the Domain 1—Proposed Approach; the 601 urban hospitals also were the majority (77.3 percent) of hospitals in the top quartile. For the Domain 1—Alternative Approach, there were 1,772 urban hospitals (72.0 percent) not in the top quartile score; the 1,772 urban hospitals also were the majority of hospitals (68.8 percent) not in the top quartile score. There were 689 urban hospitals (28.0 percent) in the top quartile score for the Domain 1—Alternative Approach; the 689 urban hospitals also were the majority of hospitals (80.3 percent) in the top quartile score.

HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR DOMAIN 2 SCORE

Hospital type	In top quartile domain 2 score			Not in top quartile domain 2 score			Totals
	Number of Hospitals	Percent of total	Percent of hospital type	Number of Hospitals	Percent of total	Percent of hospital type	
Teaching status							
Teaching	104	14.9	38.5	166	6.0	61.5	270
Non-teaching	585	84.2	19.2	2,456	89.3	80.8	3,041

HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR DOMAIN 2 SCORE—Continued

Hospital type	In top quartile domain 2 score			Not in top quartile domain 2 score			Totals
	Number of Hospitals	Percent of total	Percent of hospital type	Number of Hospitals	Percent of total	Percent of hospital type	
No information	7	1.0	5.2	127	4.6	94.8	134
Total	696	–	20.2	2,749	–	–	3,445
DSH Status							
DSH	566	81.3	21.4	2,076	75.5	78.6	2,642
Non-DSH	129	18.5	17.4	612	22.3	82.6	741
No information	1	0.1	1.6	61	2.2	98.4	62
Total	696	–	20.2	2,749	–	–	3,445
Bed Size							
Under 50	17	2.4	2.6	641	23.3	97.4	658
50–99	54	7.8	8.0	624	22.7	92.0	678
100–199	208	29.9	23.5	676	24.6	76.5	884
200–299	203	29.2	40.7	296	10.8	59.3	499
300–399	96	13.8	36.4	168	6.1	63.6	264
400–499	41	5.9	33.1	83	3.0	66.9	124
500 or more	70	10.1	34.3	134	4.9	65.7	204
No information	7	1.0	5.2	127	4.6	94.8	134
Total	696	–	20.2	2,749	–	–	3,445
Ownership							
For-profit	138	19.8	18.3	617	22.4	81.7	755
Government	100	14.4	17.9	459	16.7	82.1	559
Non-profit	451	64.8	22.6	1,546	56.2	77.4	1,997
No information	7	1.0	5.2	127	4.6	94.8	134
Total	696	–	20.2	2,749	–	–	3,445
Region/Division							
Northeast	145	20.8	27.1	391	14.2	72.9	536
New England	34	4.9	23.8	109	4.0	76.2	143
Mid-Atlantic	111	15.9	28.2	282	10.3	71.8	393
Midwest	129	18.5	16.1	673	24.5	83.9	802
East North Central	97	13.9	18.4	430	15.6	81.6	527
West North Central	32	4.6	11.6	243	8.8	88.4	275
South	271	38.9	18.7	1,176	42.8	81.3	1,447
South Atlantic	132	19.0	24.0	419	15.2	76.0	551
East South Central	50	7.2	15.2	280	10.2	84.8	330
West South Central	89	12.8	15.7	477	17.4	84.3	566
West	151	21.7	22.9	509	18.5	77.1	660
Mountain	39	5.6	16.1	203	7.4	83.9	242
Pacific	112	16.1	26.8	306	11.1	73.2	418
Total	696	–	20.2	2,749	–	79.8	3,445
Urban/Rural							
Urban	640	92.0	25.9	1,828	66.5	74.1	2,468
Rural	55	7.9	5.7	911	33.1	94.3	966
No information	1	0.1	9.1	10	0.4	90.9	11
Total	696	–	20.2	2,749	–	79.8	3,445

The second table above shows the characteristics of the worst performing hospitals for the Domain 2 score. In the second table, of the hospitals in the top quartile for the Domain 2 score, 14.9 percent were teaching hospitals, 84.2 percent were nonteaching hospitals, 81.3 percent were disproportionate share hospitals, 18.5 percent were nondisproportionate share hospitals, 40.1 percent were hospitals with a bed size of 199 or smaller, and 64.8 percent were nonprofit. Altogether, 3445 hospitals had complete data for the Domain 2 score. Among these hospitals, the majority (3,041) were nonteaching hospitals, with the majority of these nonteaching hospitals (2,456, or 80.8 percent) not in the top quartile score. A minority of the hospitals (270) were teaching hospitals; more than half of these (166, or 61.5 percent) were not in the top quartile score for Domain 2. Of those hospitals not in the top quartile score, these nonteaching hospitals were the majority (2,456, or 89.3 percent). Most of the total 3,445 hospitals were DSHs (2,642), with a minority of the hospitals being non-DSHs (741). The majority of the DSHs (2,076, or 78.6 percent) were not in the top quartile for the Domain 2 score. While less than a quarter of DSHs (566, or 21.4 percent) were in the top quartile (that is, worst performing) Domain 2 score.

In terms of bed size, for the Domain 2 score, the majority of hospitals had less than 300 beds. The majority of these hospitals with less than 300 beds were not in the top quartile for the Domain 2 score. The majority of the hospitals (884) with less than 300 beds were in the 100–199 bed size range. Of those 884 hospitals, the majority (676, or 76.5 percent) were not in the top quartile of the Domain 2 score. The minority of hospitals had greater than 300 beds. The hospitals with 300–399 bed size range (264) had a majority of hospitals (168, or 63.6 percent) not in the top quartile score, along with the hospitals with 400–499 bed size range (124) also having a majority of hospitals (83, or 66.9 percent) not in the top quartile of the Domain 2 score. Hospitals with a 500 or more bed size range (204) also had a majority not in the

top quartile score (134, or 65.7 percent), with a double digit minority (70, or 34.3 percent) in the top quartile (that is, worst performing) Domain 2 score.

In terms of ownership, for the Domain 2 score, more than half of the total of the 3,445 hospitals were nonprofit hospitals (1,997). Of these 1,997 nonprofit hospitals, the majority (1,546, or 77.4 percent) were not in the top quartile score, while the for-profit hospitals (755) also had a majority (617, or 81.7 percent) not in the top quartile score for Domain 2.

In terms of region/division of the total 3,445 hospitals for Domain 2, the Northeast region had a total of 536 hospitals with a minority (143) in the New England region and a majority (393) in Mid-Atlantic region. The Midwest region had a total of 802 hospitals, with a majority (527) in the East North Central region and the minority (275) in the West North Central region. The South region had the majority of hospitals by a region (1,447), with the South Atlantic region (551) and the West South Central region (566) having similar amounts of hospitals and the East South Central region having the minority of hospitals (330) of the South region. The West region had a total of 660 hospitals, with a majority in the Pacific region (418) and the minority in the Mountain region (242). The South region had the largest number of hospitals (271, or 38.9 percent) in the top quartile score of Domain 2. The West North Central region had the lowest number of hospitals (32, or 4.6 percent) in the top quartile score of Domain 2, with the New England region (34, or 4.9 percent) and the Mountain region (39, or 5.6 percent) having the next lowest number of hospitals in the top quartile score of Domain 2. The South region had the largest number of hospitals (1,176, or 42.8 percent) not in the top quartile of the Domain 2 score, with the New England region having the lowest number of hospitals (109, or 4.0 percent) not in the top quartile of the Domain 2 score. The Mountain region (203, or 7.4 percent) and the West North Central region (243, or 8.8 percent) having the next lowest number of hospitals not in the top quartile of the Domain 2 score.

In terms of urban/rural location of the total 3,445 hospitals, for Domain 2, the majority of hospitals (2,468) were urban, with a minority of hospitals (966) being rural. Of the total 2,468 urban hospitals, there were 1,828 urban hospitals (74.1 percent) not in top quartile of the Domain 2 score. The 1,828 urban hospitals also were the majority of hospitals (66.5 percent) not in top quartile of the Domain 2 score. There were 640 urban hospitals (25.9 percent) in the top quartile of the Domain 2 score. The 640 urban hospitals also were the majority of hospitals (92.0 percent) in the top quartile of the Domain 2 score.

HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR TOTAL HAC SCORE—DOMAIN 1—PROPOSED APPROACH AND DOMAIN 1—ALTERNATIVE APPROACH

Hospital type	In top quartile for total HAC score for domain 1—proposed approach			Not in top quartile for total HAC score for domain 1—proposed approach			Domain 1 proposed approach totals	In Top quartile for total HAC score for domain 1—alternative approach			Not in top quartile for total HAC score for domain 1—alternative approach			Domain 1 alternative approach totals
	Number of hospitals	Percent of total	Percent of hospital type	Number of hospitals	Percent of total	Percent of hospital type		Number of hospitals	Percent of total	Percent of hospital type	Number of hospitals	Percent of total	Percent of hospital type	
Teaching status														
Teaching	153	17.8	56.7	117	4.5	43.3	270	138	16.5	51.1	132	5.1	48.9	270
Non-teaching	691	80.5	22.8	2,346	91.0	77.2	3,037	687	82.2	22.6	2,350	90.4	77.4	3,037
No information	14	1.6	10.9	114	4.4	89.1	128	11	1.3	8.6	117	4.5	91.4	128
Total	858	.....	25.0	2,577	.....	.....	3,435	836	.....	24.3	2,599	.....	.....	3,435
DSH Status														
DSH	713	83.1	27.0	1,928	74.8	73.0	2,641	687	82.2	26.0	1,954	76.0	74.0	2,641
Non-DSH	140	16.3	18.9	600	23.3	81.1	740	144	17.2	20.2	569	22.1	79.8	713
No information	5	0.6	9.3	49	1.9	90.7	54	5	0.6	9.3	49	1.9	90.7	54
Total	858	.....	25.0	2,577	.....	.....	3,435	836	.....	24.5	2,572	.....	.....	3,408
Bed Size														
Under 50	47	5.5	7.2	609	23.6	92.8	656	69	8.3	10.5	587	22.6	89.5	656
50–99	105	12.2	15.5	573	22.2	84.5	678	144	17.2	21.2	534	20.5	78.8	678
100–199	237	27.6	26.8	647	25.1	73.2	884	234	28.0	26.5	650	25.0	73.5	884
200–299	186	21.7	37.3	313	12.1	62.7	499	148	17.7	29.7	351	13.5	70.3	499
300–399	105	12.2	39.9	158	6.1	60.1	263	86	10.3	32.7	177	6.8	67.3	263
400–499	59	6.9	47.6	65	2.5	52.4	124	57	6.8	46.0	67	2.6	54.0	124
500 or more	105	12.2	51.7	98	3.8	48.3	203	87	10.4	42.9	116	4.5	57.1	203
No information	14	1.6	10.9	114	4.4	89.1	128	11	1.3	8.6	117	4.5	91.4	128
Total	858	.....	25.0	2,577	.....	.....	3,435	836	.....	24.3	2,599	.....	.....	3,435
Ownership														
For-profit	166	19.3	22.0	588	22.8	78.0	754	162	19.4	21.5	592	22.8	78.5	754
Government	136	15.9	24.4	422	16.4	75.6	558	139	16.6	24.9	419	16.1	75.1	558
Non-profit	542	63.2	27.2	1,453	56.4	72.8	1,995	524	62.7	26.3	1,471	56.6	73.7	1,995
No information	14	1.6	10.9	114	4.4	89.1	128	11	1.3	8.6	117	4.5	91.4	128
Total	858	.....	25.0	2,577	.....	.....	3,435	836	.....	24.3	2,599	.....	.....	3,435
Region/Division														
Northeast	168	19.6	31.5	365	14.2	68.5	533	155	18.5	29.1	378	14.5	70.9	533
New England	41	4.8	28.7	102	4.0	71.3	143	39	4.7	27.3	104	4.0	72.7	143
Mid-Atlantic	127	14.8	32.6	263	10.2	67.4	390	116	13.9	29.7	274	10.5	70.3	390
Midwest	176	20.5	22.0	625	24.3	78.0	801	184	22.0	23.0	617	23.7	77.0	801
East North Central	127	14.8	24.1	399	15.5	75.9	526	130	15.6	24.7	396	15.2	75.3	526
West North Central	49	5.7	17.8	226	8.8	82.2	275	54	6.5	19.6	221	8.5	80.4	275
South	326	38.0	22.5	1,120	43.5	77.5	1,446	303	36.2	21.0	1,143	44.0	79.0	1,446
South Atlantic	154	17.9	27.9	397	15.4	72.1	551	137	16.4	24.9	414	15.9	75.1	551
East South Central	62	7.2	18.8	267	10.4	81.2	329	59	7.1	17.9	270	10.4	82.1	329
West South Central	110	12.8	19.4	456	17.7	80.6	566	107	12.8	18.9	459	17.7	81.1	566
West	188	21.9	28.7	467	18.1	71.3	655	149	23.2	29.6	461	17.7	70.4	655
Mountain	56	6.5	23.3	184	7.1	76.7	240	63	7.5	26.3	177	6.8	73.8	240
Pacific	132	15.4	31.8	283	11.0	68.2	415	131	15.7	31.6	284	10.9	68.4	415
Total	858	.....	25.0	2,577	.....	75.0	3,435	836	.....	.....	2,599	.....	.....	3,435
Urban/Rural														
Urban	731	85.2	29.7	1,730	67.1	70.3	2,461	691	82.7	28.1	1,770	68.1	71.9	2,461
Rural	127	14.8	13.2	837	32.5	86.8	964	145	17.3	15.0	819	31.5	85.0	964
No information	0	0.0	0.0	10	0.4	100.0	10	0	0.0	0.0	10	0.4	100.0	10
Total	858	.....	25.0	2,577	.....	75.0	3,435	836	.....	24.3	2,599	.....	75.7	3,435

The third table above shows the characteristics of the worst performing hospitals by the Total HAC Score for Domain 1—Proposed Approach and for Domain 1–Alternative Approach. In the third table, of the hospitals in the top quartile for total HAC score (Domain 1—Proposed Approach), 17.8 percent were teaching hospitals, 80.5 percent were nonteaching hospitals, 83.1 percent were disproportionate share hospitals, 16.3 percent were nondisproportionate share hospitals, 45.3 percent were hospitals with a bed size of 199 or smaller, and 63.2 percent were nonprofit. In the third table, of the hospitals in the top quartile for total HAC score (Domain 1—Alternative Approach), 16.5 percent were teaching hospitals, 82.2 percent were nonteaching hospitals, 82.2 percent were disproportionate share hospitals, 17.2 percent were nondisproportionate share hospitals, 53.5 percent were hospitals with a bed size of 199 or smaller, and 62.7 percent were nonprofit. Altogether, 3,435 hospitals had complete data for both the Domain 1—Proposed Approach, and the Domain 1—Alternative Approach. Among these hospitals, the majority (3,037) were nonteaching hospitals, with the majority of these nonteaching hospitals (2,346, or 77.2 percent for the proposed approach, and 2,350, or 77.4 percent for the alternative approach) not in the top quartile total HAC score. A minority of these hospitals (270) were teaching hospitals and slightly more than half of these hospitals (153, or 56.7 percent for the proposed approach, and 138, or 51.1 percent in the alternative approach) were in the top quartile (that is, worst performing) for the Domain 1—Proposed Approach Score and the Domain 1—Alternative Approach score. Of those hospitals not in the top quartile score, the nonteaching hospitals were the majority (2,346, or 91.0 percent for the proposed approach, and 2,350, or 90.4 percent for the alternative approach). Of the total 3,435 hospitals, the majority were DSHs (2,641), with a minority being non-DSHs (740 for the proposed approach and 713 for the alternative approach). The majority of the DSHs (1,928, or 73.0 for the proposed approach, and 1,954 or 74.0 percent for the alternative approach) were not in the top quartile for the total HAC score. While slightly more than a quarter of DSHs (713, or 27.0 percent for the proposed approach, and 687, or 26.0 percent for the alternative approach) were in the top quartile (that is, worst performing) for the total HAC score.

In terms of bed size, for the Domain 1—Proposed Approach and the Domain 1—Alternative Approach, the majority of hospitals had less than 300 beds. The majority of these hospitals with less than 300 beds were in not in the top quartile for the total HAC score. The majority of hospitals (884) with less than 300 beds were in the 100–199 bed size range. Of those 884 hospitals, the majority of hospitals (647, or 73.2 percent for the proposed approach, and 650, or 73.5 percent for the alternative approach) were not in the top quartile of total HAC score. The minority of hospitals had greater than 300 beds. Of those hospitals with greater than a 300-bed size range, the hospitals with the 300–399 bed size range (263) had a majority of hospitals (158, or 60.1 percent for the proposed approach, and 177, or 67.3 percent, for the alternative approach) not in the top quartile of total HAC score. The hospitals with 400–499 bed size range (124) also had a slight majority of hospitals (65, or 52.4 percent, for the proposed approach, and 67, or 54.0 percent, for the alternative approach) not in the top quartile of the total HAC score. Hospitals with a 500 or more bed size range (203) had a slight majority in the top quartile' section (that is, worst performing) of 105 (or 51.7 percent) for the proposed approach, and 87 (or 42.9 percent) of hospitals for the alternative approach, with a double digit minority (98, or 48.3 percent) not in the top quartile for the Domain 1—Proposed Approach total HAC score, and a slight majority (116, or 57.1 percent) not in the top quartile for the Domain 1—Alternative Approach total HAC score.

In terms of ownership, for the Domain 1—Proposed Approach and Domain 1—Alternative Approach total HAC score, more than half of the total 3435 hospitals were non-profit hospitals (1,995). Of these 1,995 nonprofit hospitals, the majority (1,453, or 72.8 percent, for the proposed approach, and 1,471, or 73.7 percent for the alternative approach) were not in top quartile of the total HAC score, while the 754 for-profit hospitals also had a majority (588, or 78.0 percent, for the proposed approach, and 592, or 78.5 percent for the alternative approach) not in the top quartile of the total HAC score.

In terms of region/division of the total 3,435 hospitals for Domain 1—Proposed Approach and the Domain 1—Alternative Approach, the Northeast region had a total of 533 hospitals, with a minority (143) in the New England region and a majority (390) in Mid-Atlantic region. The Midwest region had a total of 801 hospitals, with a majority (526) in the East North Central region and the minority (275) in the West North Central region. The South region had the majority of hospitals by a region (1,446), with the South Atlantic region (551) and the West South Central region (566) having similar numbers of hospitals and the East South Central region having the minority of hospitals (329) of the South region. The West region had a total of 655 hospitals, with a majority in the Pacific region (415) and the minority in the Mountain region (240). The South region had the largest number of hospitals (326, or 38.0 percent, for the proposed approach, and 303, or 36.2 percent, for the alternative approach) in the top quartile of the total HAC score. The New England region had the lowest number of hospitals (41, or 4.8 percent, for the proposed approach, and 39, or 4.7 percent, for the alternative approach) in the top quartile for the total HAC score, with the West North Central region (49, or 5.7 percent for the proposed approach, and 54, or 6.5 percent, for the alternative approach) and the Mountain region (56, or 6.5 percent) having the next lowest number of hospitals in the top quartile of the Domain 1—Proposed Approach total HAC score and the East South Central region (59 or 7.1 percent) having the next lowest number in the top quartile for the Domain 1—Alternative Approach total HAC score. The South region had the largest number of hospitals (1,120, or 43.5 percent, for the proposed approach, and 1,143, or 44.0 percent, for the alternative approach) not in the top quartile of the total HAC score, with the New England region having the lowest number of hospitals (102, or 4.0 percent, for the proposed approach, and 104, or 4.0 percent, for the alternative approach) not in the top quartile of the total HAC score. The Mountain region (184, or 7.1 percent, for the proposed approach, and 177, or 6.8 percent for the alternative approach) and the West North Central region (226, or 8.8 percent, for the proposed approach, and 221, or 8.5 percent for the alternative approach) had the next lowest number of hospitals not in the top quartile of the total HAC score.

In terms of urban/rural location of the total 3,435 hospitals for the Domain 1—Proposed Approach total HAC score and the Domain 1—Alternative Approach total HAC score, the majority of hospitals (2,461) were urban, with a minority of hospitals (964) being rural. Of the total 2,461 urban hospitals, there were 1,730 urban hospitals (70.3 percent) not in the top quartile of the total HAC score for the Domain 1—Proposed Approach, and 1,770 urban hospitals (71.9 percent) not in the top quartile of the total HAC score for the Domain 1—Alternative Approach. The 1,730 urban hospitals also were the majority (67.1 percent) of hospitals not in the top quartile of Domain 1—Proposed Approach total HAC score, and the 1,770 urban hospitals also were the majority (68.1 percent) of hospitals not in the top quartile of Domain 1—Alternative Approach total HAC score. There were 731 urban hospitals (29.7 percent) in the top quartile of the Domain 1—Proposed Approach total HAC score, with also a majority of hospitals (85.2 percent) in the top quartile. There were 691 urban hospitals (28.1 percent) in the top quartile of the Domain 1—Alternative Approach total HAC score, with also a majority of hospitals (82.7 percent) in the top quartile.

HOSPITALS' COMPLETENESS OF DATA FOR DOMAINS 1 AND 2

Hospital has complete data for Domain 1 (that is, data for at least 3 measures for the Domain 1-Proposed Approach or enough data to calculate PSI 90 for the Domain 1-Alternative Approach)	Hospital has complete data for Domain 2 (that is, has data for at least 1 measure for the domain)						Total No. of hospitals by type	Total percent by hospital type
	Yes			No				
	No. of hospitals	Percent of total	Percent of hospital type	No. of hospitals	Percent of total	Percent of hospital type		
YES								
Teaching	265	13.8	98.1	5	0.3	1.9	270	7.9
Non-teaching	1,643	85.3	54.1	1,394	92.4	45.9	3,037	88.4
No information	19	1.0	14.8	109	7.2	85.2	128	3.7
Subtotal	1,927			1,508			3,435	
DSH	1,564	81.2	59.2	1,077	71.4	40.8	2,641	76.9
Non-DSH	359	18.6	48.5	381	25.3	51.5	740	21.5
No information	4	0.2	7.4	50	3.3	92.6	54	1.6
Subtotal	1,927			1,508			3,435	
For-profit	365	18.9	48.4	389	25.8	51.6	754	22.0
Government	221	11.5	39.6	337	22.3	60.4	558	16.2
Non-profit	1,322	68.6	66.3	673	44.6	33.7	1995	58.1
No information	19	1.0	14.8	109	7.2	85.2	128	3.7
Subtotal	1,927			1,508			3,435	
< 50 beds	12	0.6	1.8	644	42.7	98.2	656	19.1
50–99 beds	164	8.5	24.2	514	34.1	75.8	678	19.7
100–199 beds	665	34.5	75.2	219	14.5	24.8	884	25.7
200–299 beds	486	25.2	97.4	13	0.9	2.6	499	14.5
300–399 beds	259	13.4	98.5	4	0.3	1.5	263	7.7
400–499 beds	121	6.3	97.6	3	0.2	2.4	124	3.6
500+ beds	201	10.4	99.0	2	0.1	1.0	203	5.9
No information	19	1.0	14.8	109	7.2	85.2	128	3.7
Subtotal	1,927			1,508			3,435	
NO								
Teaching	0	0.0	0.0	0	0.0	0.0	0	0.0
Non-teaching	0	0.0	0.0	4	40.0	100.0	4	40.0
No information	0	0.0	0.0	6	60.0	100.0	6	60.0
Subtotal	0			10			10	
DSH	0	0.0	0.0	1	10.0	0.0	1	10.0
Non-DSH	0	0.0	0.0	1	10.0	100.0	1	10.0
No information	0	0.0	0.0	8	80.0	100.0	8	80.0
Subtotal	0			10			10	
For-profit	0	0.0	0.0	1	10.0	100.0	1	10.0
Government	0	0.0	0.0	1	10.0	100.0	1	10.0
Non-profit	0	0.0	0.0	2	20.0	100.0	2	20.0
No information	0	0.0	0.0	6	60.0	100.0	6	60.0
Subtotal	0			10			10	
< 50 beds	0	0.0	0.0	2	20.0	100.0	2	20.0
50–99 beds	0	0.0	0.0	0	0.0	0.0	0	0.0
100–199 beds	0	0.0	0.0	0	0.0	0.0	0	0.0
200–299 beds	0	0.0	0.0	0	0.0	0.0	0	0.0
300–399 beds	0	0.0	0.0	1	10.0	100.0	1	10.0
400–499 beds	0	0.0	0.0	0	0.0	0.0	0	0.0
500+ beds	0	0.0	0.0	1	10.0	100.0	1	10.0
No information	0	0.0	0.0	6	60.0	100.0	6	60.0
Subtotal	0	0.0	0.0	10			*10*	

The fourth table above contains information on hospitals that had complete data for Domain 1 (that is, had complete data for at least 3 measures for the Domain 1-Proposed Approach or had enough data to calculate PSI 90 for the Domain 1-Alternative Approach) and hospitals that had complete data for Domain 2 (that is, had data for at least 1 measure for the domain). Altogether, 3,435 hospitals had complete data for Domain 1, regardless of whether the proposed approach or the alternative approach was selected.[193] Among these hospitals, 3,037 (88.4 percent) were nonteaching hospitals, while 270 (7.9 percent) were teaching hospitals. Most of these hospitals were DSHs (2,641, or 76.9 percent), slight more than a fifth (740, or 21.5 percent) were non-DSHs. More than half of these 3,435 hospitals were non-profit (1,995, or 58.1 percent). For-profit hospitals accounted for slightly more than one-fifth (754, or 22 percent) of the 3,435 hospitals with complete data for Domain 1, while 16.2 percent (558) were government hospitals.[194] In terms of bed size, almost 40 percent of the 3,435 hospitals were small facilities, with fewer than 100 beds. Slightly, more than a quarter (884, or 25.7 percent) had 100 to 199 beds, while the remaining 31.7 percent had at least 200 beds. We have no information about the teaching status, ownership, or bed size for 128 of the 3,435 hospitals that had complete data for Domain 1, or the DSH status of 54 of these hospitals.

Of the 3,435 hospitals with complete data for Domain 1, more than half (1,927, or 56.1 percent) also had complete data for Domain 2. Among the 1,927 hospitals with complete data for both domains, the majority were nonteaching hospitals (1,643, or 85.3 percent), DSHs (1,564, or 81.2 percent), and nonprofit hospitals (1,322, or 68.6 percent). More than 40 percent of these 1,927 hospitals had fewer than 200 beds, a quarter (486, or

[193] The reason that there were 3,435 hospitals with complete data for Domain 1, regardless of options, has to do with the minimum measure criterion for Domain 1, Option 1. In particular, a hospital had to have complete data for at least 3 measures in Domain 1-Proposed Approach to have a Domain 1 score calculated. According to the data that CMS used to develop the scoring method for implementing section 3008 of the Affordable Care Act, 3,435 hospitals had complete data for at least 3 measures in Domain 1-Proposed Approach to calculate a Domain 1 score. As for Domain 1-Alternative Approach, for hospitals that did not have enough cases to calculate any one of the eight component indicators for PSI 90, the rate for that component indicator was substituted by the national rate for that component indicator to calculate the hospital's rate for PSI 90.

[194] Government hospitals include military hospitals, hospitals run by the U.S. Department of Veteran Affairs, U.S. Department of Justice, and the Indian Health Service.

25.2 percent) had 200 to 299 beds, while more than 30 percent had 300 or more beds. Among the 1,508 hospitals with complete data for Domain 1 but not for Domain 2, the vast majority were nonteaching hospitals (1,394, or 92.4 percent); almost three-quarters of these hospitals were DSHs (1,077, or 71.4 percent). Nonprofit hospitals (673, or 44.6 percent) and small hospitals with fewer than 50 beds (644, or 42.7 percent) accounted for a considerable minority among these 1,508 hospitals.

In addition, among the 3,435 hospitals with complete data for Domain 1, the proportion of teaching hospitals that also had complete data for Domain 2 far exceeded that of those that did not (98.1 percent versus 1.9 percent). The proportion of nonteaching hospitals that had complete data was also higher than the proportion of those hospitals that did not, but the difference was smaller (54.1 percent versus 45.9 percent). DSHs were 18.4 percent more likely to have complete data for both domains than for only Domain 1; non-DSHs, on the other hand, were 3 percent more likely to have complete data for only Domain 1 than for both domains. For-profit and government hospitals were more likely to have complete data for Domain 1 only (51.6 percent and 60.4 percent, respectively) than for both domains (48.4 percent and 39.6 percent, respectively), while nonprofit hospitals were less likely to have complete data for Domain 1 only than for both domains (66.3 percent versus 33.7 percent). In terms of bed size, hospitals with more beds were more likely to have complete data for both domains, while those with fewer than 100 beds were more likely to have complete data for Domain 1 only than for both domains.

Among the 3,435 hospitals in our analysis, none had complete data for only Domain 2 but not Domain 1. Ten of the 3,435 hospitals had no complete data for either Domain 1 or Domain 2. Among these 10 hospitals, none were teaching hospitals and 4 were nonteaching hospitals. One hospital was a DSH; another was not. One hospital was a for-profit hospital, one was a government hospital, and two were nonprofit hospitals. Two of the 10 hospitals had fewer than 50 beds, 1 hospital had 300 to 399 beds, and another was a large hospital with at least 500 beds. Of these 10 hospitals, there were 6 hospitals for which we had no information about their teaching status, ownership, or bed size, and 8 hospitals for which we have no information about whether or not they were DSH.

7. Effects of the Policy Changes Relating to Payments for GME and IME

In section V.J.2. of the preamble of this proposed rule, we discuss our proposal to include labor and delivery days in the Medicare utilization calculation. We are proposing, consistent with the inpatient day counting rules for DSH as clarified in the FY 2010 IPPS/RY 2010 LTCH PPS final rule, that effective for cost reporting periods beginning on or after October 1, 2013, for purposes of applying the Medicare utilization ratio, we would include labor and delivery inpatient days in the numerator (to the extent that there are any labor and delivery inpatient days associated with Medicare beneficiaries), and all labor and delivery inpatient days in the denominator (associated with all inpatients of the hospital). In addition to payments for direct GME, we believe this proposal also would affect other Medicare policies where either the number of inpatient days or a ratio of Medicare inpatient days to total inpatient days is used to determine eligibility or payment. However, this proposal would not impact Medicare payments calculated on a reasonable cost basis for routine inpatient services, which are apportioned in accordance with 42 CFR 413.53(a)(1). We believe including labor and delivery days in the Medicare utilization calculation would result in a savings of approximately $15 million for FY 2014.

In section V.J.3. of the preamble of this proposed rule, in accordance with section 5506 of the Affordable Care Act which instructs the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is March 23, 2008), we notify the public of the closure of one teaching hospital and the initiation of another round of the section 5506 application and selection process to redistribute FTE resident slots. We are initiating ''Round 4'' of section 5506, to redistribute the FTE resident slots of the Peninsula Hospital Center in Far Rockaway, NY, which closed on April 9, 2012. We are merely using this proposed rule as a vehicle to initiate another round of the section 5506 application and selection process, which is an ongoing provision triggered each time a teaching hospital closes. Therefore, there is no impact for this provision.

In section V.J.4. of the preamble of this proposed rule, we are proposing that another IPPS or IPPS-excluded hospital may not count the resident(s) training at the CAH for IME and/or direct GME purposes, even if that hospital is paying for the residents' salary and fringe benefits. Specifically, we are proposing that, effective for portions of cost reporting periods occurring on or after October 1, 2013, a hospital may not claim the FTE residents that are training at a CAH for IME and/or direct GME purposes. However, under policies that were applicable prior to October 1, 2013 and that continue to apply on and after October 1, 2013, the CAH may incur the costs of training the FTE residents for the time that the FTE residents rotate to the CAH, and receive payment based on 101 percent of its Medicare reasonable costs under 42 CFR 413.70.

We do not believe that there is any financial impact of this proposed policy, as we are not precluding all Medicare payment for residents training at CAHs. Rather, we are precluding payment to one group of providers (that is, hospitals), but continuing to allow payment to another group (that is, CAHs). Under current policy, either a hospital could receive IME and direct GME payment for the time spent by residents training at a CAH if the hospital incurred the cost of that training, *or* the CAH could receive payment under § 413.70 if the CAH incurred the training cost. Under the proposed policy, hospitals would no longer be allowed to receive IME and direct GME payment for the costs associated with training residents at a CAH. However, CAHs could continue to receive payment under § 413.70 for the allowable costs associated with training residents at a CAH in approved residency training programs.

In section V.J.5. of the preamble of this proposed rule, we discuss the provisions of section 711 of the Medicare Modernization Act (Pub. L. 108–173) which amended section of 1886(h)(2)(D)(iv)(I) of the Act to freeze annual CPI–U updates to hospital-specific PRAs for direct GME payment purposes for those PRAs that exceed the ceiling for FYs 2004 through 2013. Therefore, the ''freeze'' for PRAs that exceed the ceiling expires beginning in FY 2014. That is, for cost reporting periods beginning on or after October 1, 2013, the usual full CPI–U update, as determined under 42 CFR 413.77(c)(1) would apply to all PRAs for direct GME payment purposes. We note that we are not making any proposals related to this provision in this proposed rule. We are merely providing notice to the public that a statutory provision will no longer apply in FY 2014.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section V.K. of the preamble of this proposed rule, 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 ''[i]n 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 V.K. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 9 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 proposing to adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are proposing to apply budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that 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 proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. The proposed adjustment to the national IPPS rates to account for estimated demonstration cost for FY 2014 for the 7 ''pre-expansion'' participating hospitals that are currently

participating in the demonstration and the 16 additional hospitals participating as a result of the expansion of the demonstration under the Affordable Care Act is $46,515,865. In addition, in this FY 2014 proposed rule, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009, or 2010) are made available prior to the FY 2014 IPPS/LTCH PPS final rule, we would incorporate into the FY 2014 budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. The estimated amount of $46,515,865 that we are proposing for FY 2014 does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration for FYs 2007 through 2010 and the amounts that were offset by the budget neutrality adjustment for these years because the specific numeric value associated with this component of the adjustment to the national IPPS rates cannot be known at this time. This is because the large majority of settled cost reports beginning in FYs 2007 through 2010 for the hospitals participating in the demonstration during those years also are not available at this time.

9. Effects of the Extended Effective Date for Policy on Hospital Services Furnished Under Arrangements

In section V.M. of the preamble of this proposed rule, we discuss our proposed change in the implementation date of our revised policy, as outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711) under which we limit the circumstances under which a hospital may furnish services to Medicare beneficiaries ''under arrangements.'' We are proposing to change the implementation date of the requirement to be effective for services provided on or after January 1, 2015 (instead of effective with cost reporting periods beginning on or after October 1, 2013). Because there are hospitals in the midst of significant building projects that, when completed, will enable the hospital to provide routine services in compliance with the requirements of this revised policy, we believe it is appropriate to further delay the effective date. We expect that, with the additional time before the revised ''under arrangement'' policy becomes effective, hospitals will complete the work needed to ensure compliance with the new requirement. Effective for services provided on or after January 1, 2015, all hospitals would need to be in full compliance with the revised policy for services furnished under arrangement. We have determined that the impact of this proposed effective date change would be negligible.

I. Effects of Proposal Relating to the Furnishing of Acute Care Inpatient Services by CAHs

In section VII.B.2. of the preamble of this proposed rule, we discuss our proposal to revise the requirements under the CoPs for CAHs to specify that CAHs must provide acute care inpatient services. We estimate that the costs to CAHs to implement this proposal would be minimal. The vast majority of CAHs, approximately 99 percent, already are providing acute care inpatient services. In fact, we believe that most CAHs would not consider the proposal a change in policy. We believe most CAHs will view this proposal as a clarification that confirms their usual and customary business practices. We welcome public comments on our assumptions and estimates.

J. Effects of Proposed Changes to the CoPs for Hospitals Relating to the Administration of Pneumococcal Vaccines

In section X. of the preamble of this proposed rule, we discuss our proposal to amend the standard under the CoPs for hospitals relating to the administration of pneumococcal vaccine by nursing staff. We are proposing to delete the term ''polysaccharide'' vaccine in the standard to allow hospitals to include any type of pneumococcal vaccine as part of its physician-approved policy for administration by nurses without a prior practitioner order.

While we expect this proposed change to have a positive effect on hospitals by providing them with additional regulatory flexibility in this area, it is difficult to estimate this positive effect in terms of actual cost savings for hospitals. We believe that the proposed change would carry the additional benefit of improving patient access to pneumococcal vaccines if hospitals choose to exercise the potential regulatory flexibility proposed and purchase and stock more than one type of pneumococcal vaccine as a result. This benefit would be particularly apparent if there were a shortage of one type of the pneumococcal vaccine in the future. In conclusion, while we cannot estimate any cost savings that would result from this proposed change, we are confident that it would not impose any burden on hospitals.

K. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2012 update of the FY 2012 MedPAR file and the December 2012 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2012 update of the most recently available hospital cost report data (FYs 2010 and 2011) 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 proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2012 update of the FY 2012 MedPAR file, we simulated payments under the capital IPPS for FY 2013 and FY 2014 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 capital IPPS payments in FY 2014 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 also receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index would increase by 0.5 percent in both FYs 2013 and 2014.
- We estimate that Medicare discharges would be approximately 12.3 million in FY 2013 and 12.7 million in FY 2014.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this proposed rule, the proposed update is 0.90 percent for FY 2014.
- In addition to the proposed FY 2014 update factor, the proposed FY 2014 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9988, a proposed outlier adjustment factor of 0.9451, and a proposed adjustment factor of 0.9980 to offset the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A, as discussed in section VI.C. of the preamble of this proposed rule.

2. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2014 on total capital payments per case, using a universe of 3,404 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2012 update of the FY 2012 MedPAR file, the December 2012 update to the PSF, and the most recent cost report data from the December 2012 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2013 and estimated total payments per case

for FY 2014 based on the proposed FY 2014 payment policies. Column 2 shows estimates of payments per case under our model for FY 2013. Column 3 shows estimates of payments per case under our model for FY 2014. Column 4 shows the proposed total percentage change in payments from FY 2013 to FY 2014. The proposed change represented in Column 4 includes the proposed 0.90 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2014 are expected to increase as compared to capital payments per case in FY 2013. The proposed capital Federal rate for FY 2014 would increase approximately 1.5 percent as compared to the FY 2013 capital Federal rate. Overall, across all hospitals, the proposed changes to the GAFs are expected to have no net effect on capital payments. However, regionally, the effect of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index) as shown in Table I in section I.G. of this Appendix.

We are estimating a slight decrease in outlier payments in FY 2014 as compared to FY 2013. This is primarily because of the proposed increase to the proposed outlier fixed-loss amount (discussed in section II.A.4.f. of the Addendum to this proposed rule).

The net impact of these proposed changes is an estimated 1.1 percent change in capital payments per discharge from FY 2013 to FY 2014 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, with the exception of one region, all hospitals are expected to experience an increase in capital IPPS payments per case in FY 2014 as compared to FY 2013. These expected increases are primarily due to the proposed increase in the capital Federal rate, but are somewhat offset by the projected decrease in payments because of the proposed GAFs, and the projected decrease in outlier payments. Capital IPPS payments per case for both large urban hospitals and other urban hospitals are estimated to increase 1.2 percent. Rural hospitals, on average, are expected to experience a 0.6 percent increase in capital payments per discharge from FY 2013 to FY 2014. The factors contributing to the difference in the projected increase in capital IPPS payments per discharge for urban hospitals as compared to rural hospitals are a decrease in capital payments to rural hospitals due to proposed changes to the GAF, a relatively larger decrease in projected outlier payments to rural hospitals, and a relatively lower projected increase in capital payments to rural hospitals due to the proposed changes to the MS–DRG relative weights.

The comparisons by region show that the estimated increases in capital payments per discharge from FY 2013 to FY 2014 in urban areas ranges from a 2.3 percent increase for the New England urban region to a 0.6 percent increase for the Mountain urban region. Similarly, for rural regions, the New England rural region is expected to experience the largest increase in capital IPPS payments per discharge at 1.7 percent. Unlike most other urban and rural regions, for both the New England urban and rural region, a large part of the expected increase in capital IPPS payments per discharge is due to the proposed GAFs, which are consistent with the proposed changes in the wage index for hospitals located in the New England area, as discussed in section I. of this Appendix.

Whereas all urban regions and most rural regions are estimated to experience an increase in capital IPPS payments per discharge, the Mountain rural region is expected to experience a 0.1 percent decrease in capital IPPS payments per discharge—the only region not expected to experience an increase. This is mainly due both to projected decreases in capital payments in FY 2014 resulting from the proposed changes to the GAFs, as well as proposed changes to the outlier threshold.

All but one of the hospitals located in Puerto Rico are in urban areas. Hospitals located in the Puerto Rico urban region are expected to experience a 2.1 percent increase in capital IPPS payments per discharge in FY 2014 as compared to FY 2013. This larger than average projected increase in capital IPPS payments per discharge is mostly due to the proposed GAFs, which are consistent with the proposed changes in the wage index for hospitals located in the Puerto Rico urban areas, as discussed in section I. of this Appendix.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are estimated to experience an increase in capital payments per case from FY 2013 to FY 2014. The proposed increase in capital payments for both government and proprietary hospitals is estimated at 1.0 percent, and voluntary hospitals are estimated to experience a 1.3 percent increase in capital payments per case from FY 2013 to FY 2014.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2014. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2014, we show the average capital payments per case for reclassified hospitals for FY 2014. Urban reclassified hospitals are expected to experience a 1.6 percent increase in capital payments, whereas urban nonreclassified hospitals are expected to experience an increase of 1.1 percent. The proposed estimated percentage increase for rural reclassified hospitals is 1.1 percent. However, rural nonreclassified hospitals are expected to experience a 0.2 percent decrease in capital payments per case. Other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience a 1.3 percent increase in capital payments from FY 2013 to FY 2014.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2013 Payments Compared To FY 2014 Payments]

	Number of hospitals	Average FY 2013 payments/case	Average FY 2014 payments/case	Change
By Geographic Location:				
All hospitals	3,404	816	826	1.1
Large urban areas (populations over 1 million)	1,367	903	914	1.2
Other urban areas (populations of 1 million of fewer)	1,114	794	803	1.2
Rural areas	923	564	568	0.6
Urban hospitals	2,481	854	864	1.2
0–99 beds	622	716	712	−0.5
100–199 beds	762	738	745	0.9
200–299 beds	464	786	795	1.2
300–499 beds	418	870	882	1.3
500 or more beds	215	1,016	1,031	1.5
Rural hospitals	923	564	568	0.6
0–49 beds	339	457	458	0.0
50–99 beds	328	517	521	0.7
100–149 beds	151	559	562	0.5
150–199 beds	59	628	633	0.7

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2013 Payments Compared To FY 2014 Payments]

	Number of hospitals	Average FY 2013 payments/case	Average FY 2014 payments/case	Change
200 or more beds	46	675	682	0.9
By Region:				
Urban by Region	2,481	854	864	1.2
New England	120	928	949	2.3
Middle Atlantic	318	900	920	2.2
South Atlantic	375	786	792	0.7
East North Central	395	818	825	0.9
East South Central	149	745	752	1.0
West North Central	165	851	860	1.0
West South Central	371	789	797	1.0
Mountain	156	890	896	0.6
Pacific	381	1,064	1,077	1.2
Puerto Rico	51	380	388	2.1
Rural by Region	923	564	568	0.6
New England	23	765	778	1.7
Middle Atlantic	69	581	585	0.6
South Atlantic	165	544	547	0.5
East North Central	119	586	590	0.7
East South Central	171	517	519	0.4
West North Central	100	596	602	0.9
West South Central	181	504	507	0.4
Mountain	65	617	617	−0.1
Pacific	29	723	733	1.4
Puerto Rico	1	198	210	6.2
By Payment Classification:				
All hospitals	3,404	816	826	1.1
Large urban areas (populations over 1 million)	1,377	902	913	1.2
Other urban areas (populations of 1 million of fewer)	1,118	794	803	1.2
Rural areas	909	571	574	0.5
Teaching Status:				
Non-teaching	2,378	699	704	0.7
Fewer than 100 Residents	782	803	814	1.3
100 or more Residents	244	1,148	1,166	1.6
Urban DSH:				
100 or more beds	1,562	874	886	1.3
Less than 100 beds	330	615	622	1.1
Rural DSH:	260	530	530	−0.2
Sole Community (SCH/EACH).				
Referral Center (RRC/EACH)	223	625	630	0.7
Other Rural:				
100 or more beds	29	523	521	−0.4
Less than 100 beds	294	460	461	0.3
Urban teaching and DSH:				
Both teaching and DSH	826	944	958	1.5
Teaching and no DSH	135	837	849	1.4
No teaching and DSH	1,066	737	745	1.0
No teaching and no DSH	468	770	771	0.1
Rural Hospital Types:				
Non special status hospitals	2,367	859	869	1.2
RRC/EACH	76	770	791	2.7
SCH/EACH	37	758	765	0.9
SCH, RRC and EACH	17	779	800	2.7
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2014 Reclassifications:				
All Urban Reclassified	451	849	862	1.6
All Urban Non-Reclassified	1,990	858	867	1.1
All Rural Reclassified	311	601	607	1.1
All Rural Non-Reclassified	552	513	511	−0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	53	553	560	1.3
Type of Ownership:				
Voluntary	1,944	828	839	1.3
Proprietary	895	741	748	1.0
Government	546	853	861	1.0
Medicare Utilization as a Percent of Inpatient Days:				
0–25	368	1,038	1,053	1.5
25–50	1,807	857	867	1.2
50–65	967	685	692	1.1
Over 65	171	601	606	0.8

L. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2014. In the preamble of this proposed rule, we specify the statutory authority for the proposed provisions that are presented, identify those proposed policies, and present rationales for our proposed decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, there are 423 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control) LTCHs, 327 proprietary LTCHs, and 18 LTCHs that are government-owned and operated. (We note that although there are currently approximately 440 LTCHs, for purposes of this impact analysis, we excluded the data of all inclusive rate providers and the LTCHs that are paid in accordance with demonstration projects, consistent with the development of the proposed FY 2014 MS–LTC–DRG relative weights (discussed in section VIII.B.3.c. of the preamble of this proposed rule)). In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, including the proposed 1.8 percent annual update for LTCHs that submit quality data 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 proposed second year phase of a one-time prospective adjustment factor of 0.98734 (approximately –1.3 percent), the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2014. (As discussed in section IX.C. of the preamble of this proposed rule, in accordance with section 1886(m)(5)(C) of the Act, for LTCHs that fail to submit quality data, the proposed annual update to the LTCH PPS standard Federal rate is reduced by 2.0 percentage points beginning in FY 2014.)

The standard Federal rate for FY 2013 is $40,397.96. However, consistent with the statute, the payment for FY 2013 discharges occurring on or before December 28, 2012 does not reflect the one-time prospective adjustment under § 412.523(d)(3) of the regulations, and such discharges are paid based on a standard Federal rate of $40,915.95 (77 FR 53710) . For FY 2014, we are proposing to establish a standard Federal rate of $40,622.06, which reflects the proposed 1.8 percent annual update to the standard Federal rate, and the proposed area wage budget neutrality factor of 1.000433 to ensure that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments, and the proposed second year of the phase-in of the one-time prospective adjustment factor of 0.98734. We note that the proposed factors described above to determine the proposed FY 2014 standard Federal rate are applied to the FY 2013 Federal standard rate set forth under section § 412.523(c)(3)(ix)(A) (that is, $40,397.96).

Based on the best available data for the 423 LTCHs in our database, we estimate that the proposed annual update to the standard Federal rate for FY 2014 (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2014 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated increase in HCO payments would result in an increase in estimated payments from FY 2013 of approximately $62 million. Based on the 423 LTCHs in our database, we estimate that the FY 2014 LTCH PPS payments would be approximately $5.599 billion, as compared to estimated FY 2013 LTCH PPS payments of approximately $5.537 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are over approximately $100 million, this proposed rule is considered a major economic rule, as defined in this section. We note that the approximate $62 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2013 to FY 2014 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes. (We note that this impact does not include an estimate effect of the 2.0 percentage points reduction to the proposed annual update to the LTCH PPS standard Federal rate for LTCHs that fail to submit quality data, as required by section 1886(m)(5)(C) of the Act, because we have not determined at this time which, if any, LTCHs failed to submit the requisite quality data for FY 2014 under the LTCH Quality Reporting Program.)

The projected 1.1 percent increase in estimated proposed payments per discharge from FY 2013 to FY 2014 is attributable to several factors, including the proposed 1.8 percent annual update to the standard Federal rate, the proposed one-time prospective adjustment factor for FY 2014 of 0.98734 (approximately –1.3 percent), and projected increases in estimated HCO payments. As Table IV shows, the change attributable solely to the proposed annual update to the standard Federal rate (1.8 percent), including the proposed one-time prospective adjustment factor for FY 2014 under the second year of the phase-in (approximately –1.3 percent), is projected to result in an increase of 0.5 percent in payments per discharge from FY 2013 to FY 2014, on average, for all LTCHs. We note, the estimated change in payments solely attributable to the proposed annual update to the standard Federal rate does not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute (and, therefore, are paid based on a relatively higher rate). The change in payments solely attributable to the proposed annual update to the standard Federal rate for FY 2014 would be a smaller increase in payments relative to the pre-December 29, 2012 LTCH payment rates (approximately 0.2 percent instead of 0.5 percent). In addition to the proposed 1.8 percent annual update for FY 2014 and the proposed −1.3 percent one-time prospective adjustment factor for FY 2014, this estimated increase in aggregate LTCH PPS payments of 0.5 percent also includes estimated payments for SSO cases that are paid using special methodologies that are not affected by the annual update to the standard Federal rate. Therefore, for some hospital categories, the projected increase in payments based on the proposed standard Federal rate is less than the proposed 0.5 percent annual update for FY 2014.

Because we are proposing to apply an area wage level budget neutrality factor to the standard Federal rate, the proposed annual update to the wage data and labor-related share does not impact the increase in aggregate payments. In addition, we note that the updates to the standard Federal rate to determine the estimated effects described above were applied to the FY 2013 standard Federal rate set forth under section § 412.523(c)(3)(ix)(A) (that is, $40,397.96).

As discussed in section V.B. of the Addendum to this proposed rule, we are proposing to update the wage index values for FY 2014 based on the most recent available data. In addition, we are proposing to decrease the labor-related share from 63.096 percent to 62.717 percent under the LTCH PPS for FY 2014, 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 proposing to apply an area wage level budget neutrality factor of 1.000433, which increases the proposed standard Federal rate by approximately 0.04 percent. Therefore, the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments.

Table IV below shows the impact of the proposed payment rate and the proposed policy changes on LTCH PPS payments for FY 2014 presented in this proposed rule by comparing estimated FY 2013 payments to estimated FY 2014 payments. The projected increase in payments per discharge from FY 2013 to FY 2014 is 1.1 percent (shown in Column 9). This projected increase in payments is attributable to the impacts of the proposed change to the standard Federal rate (0.5 percent in Column 6) and the effect of the estimated increase in proposed payments for HCO cases and SSO cases (0.8 percent and 0.2 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2013 to FY 2014 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2014. An analysis of the most recent available LTCH PPS claims data (that is, FY 2012 claims data from the

December 2012 update of the MedPAR file) indicates that the FY 2013 HCO threshold of $15,408 (as established in the FY 2013 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2014 that fall below the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 7.2 percent of the estimated total LTCH PPS payments in FY 2013. We estimate that the impact of the increase in HCO payments would result in approximately a 0.8 percent increase in estimated payments from FY 2013 to FY 2014, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2013 to FY 2014 for HCOs, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries. This increase in estimated costs also results in a projected increase in SSO payments of approximately 0.2 percent relative to last year. The net result of these projected changes in HCO and SSO payments in FY 2014 is an estimated change in aggregate payments of 1.0 percent. We note that estimated payments for all SSO cases comprise approximately 12 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprise approximately 8 percent of the estimated total FY 2014 LTCH PPS payments. Payments for HCO cases are based on 80 percent of the estimated cost of the case above the HCO threshold, while the majority of the payments for SSO cases (approximately 57 percent) are based on the estimated cost of the case.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts would result in appropriate Medicare payments.

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 0.7 percent increase in estimated payments per discharge for FY 2014 as compared to FY 2013 for rural LTCHs that would result from the proposed changes presented in this proposed rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 27 rural LTCHs in our database (out of 423 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2013 to FY 2014 for rural LTCHs (0.7 percent) is less than the national average increase (1.1 percent). The estimated increase in LTCH PPS payments from FY 2013 to FY 2014 for rural LTCHs is primarily due to the proposed increase to the standard Federal rate. However, rural LTCHs are experiencing slightly lower increases than the national average due to decreases in their wage index for FY 2014 compared to FY 2013.

3. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal 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.

As discussed above in section I.L.1. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately $62 million based on the 423 LTCHs in our database.

b. Expiration of Statutory Delay of Full Implementation of the ''25-Percent Threshold'' Payment Adjustment Policy and 1-Year Extension

As discussed in section VIII.D. of the preamble of this proposed rule, the statutory delay of the full application of the ''25-percent threshold'' payment adjustment for LTCHs under § 412.534 and § 412.536 expired for cost reporting periods beginning on or after July 1, 2012, or October 1, 2012, as applicable. We established a 1-year extension of the moratorium on the application of the ''25-percent threshold'' payment adjustment policy as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013 (and for discharges occurring on or after October 1, 2012, through the end of the cost reporting period of LTCHs with cost reporting periods beginning on or after July 1, 2012, and before September 30, 2012, as explained in section VIII.D. of the preamble of this proposed rule). The regulatory moratorium on the full application of the ''25-percent threshold'' payment adjustment will expire for certain LTCHs for cost reporting periods beginning on or after October 1, 2013, and as discussed in section VIII.D. of the preamble of this proposed rule, we do not anticipate extending the regulatory moratorium of the full application of the 25-percent payment adjustment threshold further. We estimate that the expiration of this moratorium will result in a payment reduction of approximately $190 million to LTCHs.

c. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth under § 412.515 through § 412.536. In addition to the basic MS–LTC–DRG payment (the standard Federal rate multiplied by the MS–LTC–DRG relative weight), we make adjustments for differences in area wage levels, the COLA for LTCHs located in Alaska and Hawaii, and SSOs. Furthermore, LTCHs may also receive HCO payments for those cases that qualify based on the threshold established each year.

To understand the impact of the proposed changes to the LTCH PPS payments presented in this proposed rule on different categories of LTCHs for FY 2014, it is necessary to estimate payments per discharge for FY 2013 using the rates, factors (including the FY 2013 GROUPER (Version 30.0), and relative weights and the policies established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53458 through 53502 and 53708 through 53716). It is also necessary to estimate the payments per discharge that would be made under the proposed LTCH PPS rates, factors, policies, and GROUPER (proposed Version 31.0) for FY 2014 (as discussed in section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). These estimates of FY 2013 and FY 2014 LTCH PPS payments 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. We also evaluated the proposed change in estimated FY 2013 payments to estimated FY 2014 payments (on a per discharge basis) for each category of LTCHs. We are proposing to establish a standard Federal rate for FY 2014 of $40,622.06 that includes the proposed 1.8 percent annual update, the proposed area wage budget neutrality factor of 1.000433, and the proposed one-time prospective adjustment to the standard Federal rate for FY 2014 of 0.98734 (approximately −1.3 percent).

Hospital groups were based on characteristics provided in the OSCAR data, FY 2009 through FY 2011 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.

To estimate the impacts of the proposed payment rates and policy changes among the various categories of existing providers, we used LTCH cases from the FY 2012 MedPAR file to estimate payments for FY 2013 and to estimate payments for FY 2014 for 423 LTCHs. We believe that the discharges based on the FY 2012 MedPAR data for the 423 LTCHs in our database, which includes 327 proprietary LTCHs, provide sufficient representation in the MS–LTC–DRGs containing discharges for patients who received LTCH care for the most commonly treated LTCH patients' diagnoses.

d. Calculation of Prospective Payments

For purposes of this impact analysis, to estimate per discharge payments under the LTCH PPS, we simulated payments on a case-by-case basis using LTCH claims from the FY 2012 MedPAR files. For modeling estimated LTCH PPS payments for FY 2013, we used the FY 2013 standard Federal rate (that is, $40,915.95 used to make payments for LTCH discharges occurring on or after October 1, 2012 through December 28, 2012, and $40,397.96 for discharges occurring on or after December 29, 2012 through September 30, 2013).

For modeling estimated LTCH PPS payments for FY 2014, we used the proposed FY 2014 standard Federal rate of $40,622.06, which includes the proposed one-time prospective adjustment of 0.98734 for FY 2014 for the second year of the 3-year phase-in. The proposed FY 2014 standard Federal rate of $40,622.06 includes the proposed application of an area wage level budget neutrality factor of 1.000433 (as discussed in section V.B.5. of the Addendum to this proposed rule). Furthermore, in modeling estimated LTCH PPS payments for both FY 2013 and FY 2014 in this impact analysis, we applied the FY 2013 and the proposed FY 2014 adjustments for area wage levels and the proposed COLA for LTCHs located in Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2013 payments using the current LTCH PPS labor-related share of 63.096 percent (77 FR 53711) and the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2013 IPPS/LTCH PPS final rule (which are available via the Internet (77 FR 53717)). We also applied the FY 2013 COLA factors shown in the table in section V.C. of the Addendum to that final rule (77 FR 53713) to adjust the FY 2013 nonlabor-related share (36.904 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2014 payments using the proposed FY 2014 LTCH PPS labor-related share of 62.717 percent and the proposed FY 2014 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also applied the proposed FY 2014 COLA factors shown in the table in section V.C. of the Addendum to this proposed rule to the proposed FY 2014 nonlabor-related share (37.283 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 increase in payments for HCO cases (as described in section V.D. of the Addendum to this proposed rule). In modeling proposed payments for SSO and HCO cases in FY 2014, we applied an inflation factor of 4.8 percent (determined by OACT) to estimate the costs of each case using the charges reported on the claims in the FY 2012 MedPAR files and the best available CCRs from the December 2012 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2014 in this impact analysis, we used the proposed FY 2014 fixed-loss amount of $14,139 (as discussed in section V.D. of the Addendum to this proposed rule).

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2013 to FY 2014 based on the proposed payment rates and policy changes presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the LTCH PPS among various classifications of LTCHs.

- 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.
- The fourth column shows the estimated payment per discharge for FY 2013 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2014 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2013 to FY 2014 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule), including the second year of the phase-in of the one-time prospective adjustment factor for FY 2014. (As noted previously, the estimate payment changes shown in this column do not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute.)
- The seventh column shows the percentage change in estimated payments per discharge from FY 2013 to FY 2014 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and proposed labor-related share), including the proposed application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge from FY 2013 (Column 4) to FY 2014 (Column 5) for all proposed changes (and includes the effect of estimated proposed changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2014 (ESTIMATED FY 2013 PAYMENTS COMPARED TO ESTIMATED FY 2014 PAYMENTS *)

LTCH Classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2013 LTCH PPS payment per case	Average FY 2014 LTCH PPS payment per case [1]	Percent change in estimated payments per discharge from FY 2013 to proposed FY 2014 for the proposed annual update to the Federal rate [2]	Percent change in estimated payments per discharge from FY 2013 to FY 2014 for proposed changes to the area wage level adjustment with proposed budget neutrality [3]	Percent change in payments per discharge from FY 2013 to FY 2014 for all proposed changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL PROVIDERS	423	140,490	$39,417	$39,856	0.5	0.0	1.1
BY LOCATION:							
RURAL	27	6,504	35,149	35,382	0.5	−0.2	0.7
URBAN	396	133,986	39,624	40,073	0.5	0.0	1.1
LARGE	197	77,541	41,615	42,133	0.4	0.1	1.2
OTHER	199	56,445	36,889	37,244	0.5	−0.1	1.0
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	16	5,621	34,969	35,400	0.4	0.1	1.2
OCT. 1983–SEPT. 1993	44	17,271	42,088	42,592	0.4	0.1	1.2
OCT. 1993–SEPT. 2002	182	64,138	38,720	39,097	0.5	−0.1	1.0
AFTER OCTOBER 2002	181	53,460	39,858	40,351	0.5	0.1	1.2
BY OWNERSHIP TYPE:							
VOLUNTARY	78	19,042	39,558	40,137	0.4	0.0	1.5
PROPRIETARY	327	118,366	39,259	39,677	0.5	0.0	1.1
GOVERNMENT	18	3,082	44,603	45,012	0.4	−0.6	0.9
BY REGION:							
NEW ENGLAND	14	7,266	34,984	35,448	0.4	0.2	1.3
MIDDLE ATLANTIC	30	8,374	41,646	42,311	0.5	0.5	1.6
SOUTH ATLANTIC	60	18,053	41,634	42,024	0.4	−0.2	0.9
EAST NORTH CENTRAL	70	20,431	40,664	41,119	0.5	−0.1	1.1
EAST SOUTH CENTRAL	31	8,792	39,386	39,843	0.5	−0.1	1.2
WEST NORTH CENTRAL	26	6,492	39,461	39,921	0.5	−0.2	1.2
WEST SOUTH CENTRAL	135	50,268	35,416	35,733	0.5	−0.1	0.9

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2014 (ESTIMATED FY 2013 PAYMENTS COMPARED TO ESTIMATED FY 2014 PAYMENTS *)—Continued

LTCH Classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2013 LTCH PPS payment per case	Average FY 2014 LTCH PPS payment per case [1]	Percent change in estimated payments per discharge from FY 2013 to proposed FY 2014 for the proposed annual update to the Federal rate [2]	Percent change in estimated payments per discharge from FY 2013 to FY 2014 for proposed changes to the area wage level adjustment with proposed budget neutrality [3]	Percent change in payments per discharge from FY 2013 to FY 2014 for all proposed changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
MOUNTAIN	32	7,034	42,722	43,279	0.5	−0.1	1.3
PACIFIC	25	13,780	48,552	49,246	0.4	0.3	1.4
BY BED SIZE:							
BEDS: 0–24	25	2,948	35,535	35,745	0.5	−0.3	0.6
BEDS: 25–49	202	47,094	38,578	38,960	0.5	0.0	1.0
BEDS: 50–74	116	38,180	40,303	40,834	0.5	0.1	1.3
BEDS: 75–124	43	20,917	41,248	41,725	0.5	0.0	1.2
BEDS: 125–199	24	17,017	38,624	38,991	0.5	−0.1	1.0
BEDS: 200+	13	14,334	38,882	39,342	0.5	0.1	1.2

[1] Estimated FY 2014 LTCH PPS payments based on the proposed payment rate and policy changes presented in the preamble and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge from FY 2013 to FY 2014 for the proposed annual update to the standard Federal rate and the proposed one-time prospective adjustment factor for FY 2014 as discussed in section V.A.2. of the Addendum to this proposed rule. Note, this column does not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute (and therefore, are paid based on a relatively higher rate).

[3] Percent change in estimated payments per discharge from FY 2013 to FY 2014 for proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge from FY 2013 LTCH PPS (shown in Column 4) to FY 2014 LTCH PPS (shown in Column 5), including all of the proposed changes presented in the preamble and the Addendum to this proposed rule. Note, this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the standard Federal rate (column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

e. Results

Based on the most recent available data for 423 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the proposed LTCH PPS payment rate and policy changes presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge are expected to increase 1.1 percent, on average, for all LTCHs from FY 2013 to FY 2014 as a result of the proposed payment rate and policy changes presented in this proposed rule, including an estimated increase in HCO payments. This estimated 1.1 percent increase in LTCH PPS payments per discharge from the FY 2013 to FY 2014 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2014 LTCH PPS payments (using the proposed payment rate and policies discussed in this proposed rule) to estimated FY 2013 LTCH PPS payments (as described above in section I.L.1. of this Appendix).

We are proposing to establish a standard Federal rate of $40,622.06 for FY 2014. Specifically, we are proposing to update the standard Federal rate for FY 2014 by 1.8 percent, which is based on the latest estimate of the proposed LTCH PPS market basket increase (2.5 percent), the proposed reduction of 0.4 percentage point for the MFP adjustment, and the 0.3 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. In addition, we are proposing to apply a one-time prospective adjustment factor for FY 2014 of 0.98734 (approximately −1.3 percent) to the standard Federal rate for the second year of the 3-year phase-in. We note that consistent with the statute, the one-time prospective adjustment to the standard Federal rate for FY 2013 is not applied to payments for discharges occurring before December 29, 2012. Therefore, payments for FY 2013 discharges occurring on or before December 28, 2012, are paid based on a standard Federal rate that does not reflect that adjustment (and, therefore, are paid based on a relatively higher rate).

We noted earlier in this section that, for most categories of LTCHs, as shown in Table IV (Column 6), the impact of the increase of 0.5 percent in the proposed annual update to the standard Federal rate and the proposed application of the one-time prospective adjustment for FY 2014 of approximately −1.3 percent for the second year of the 3-year phase-in is projected to result in approximately a 0.5 percent increase in estimated payments per discharge for all LTCHs from FY 2013 to FY 2014. (As noted previously, the estimate payment changes shown in this column were determined based on the FY 2013 standard Federal rate of $40,915.95, and do not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute.)

In addition, our estimate of the proposed changes in payments due to the proposed update to the standard Federal rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the update to the standard Federal rate. For these reasons, we estimate that payments would increase by less than 0.5 percent for certain hospital categories due to the proposed annual update to the standard Federal rate and the proposed application of the second phase of the one-time prospective adjustment for FY 2014.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 6 percent of the LTCHs are identified as being located in a rural area, and approximately 5 percent of all LTCH cases are treated in these rural hospitals. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge from FY 2013 to FY 2014 for all hospitals is 1.1 percent for all proposed changes. For rural LTCHs, the percent change for all proposed changes is estimated to be 0.7 percent, while for urban LTCHs, we estimate the increase would be 1.1 percent. Large urban LTCHs are projected to experience an increase of 1.2 percent in estimated payments per discharge from FY 2013 to FY 2014, while other urban LTCHs are projected to experience an increase of 1.0 percent in estimated payments per discharge from FY 2013 to FY 2014, 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) after October 2002. Based on the most recent available data, the

categories of LTCHs with the largest percentage of LTCH cases (approximately 46 percent) are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and hospitals that began participating in the Medicare program after October 2002, and they are projected to experience a 1.0 and 1.2 percent in estimated payments per discharge from FY 2013 to FY 2014, respectively, as shown in Table IV.

Approximately 4 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience a slightly higher than average percent increase (1.2 percent) in estimated payments per discharge from FY 2013 to FY 2014, as shown in Table IV. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are also projected to experience a 1.2 percent increase in estimated payments from FY 2013 to FY 2014.

(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). We expect that LTCHs in the voluntary category will experience a higher than the average increase (1.5 percent) in estimated FY 2014 LTCH PPS payments per discharge as compared to estimated payments in FY 2013 primarily because we project the estimated increase in HCO payments to be higher than the average increase for these LTCHs. The majority (over 77 percent) of LTCHs are identified as proprietary and these LTCHs are projected to experience the national average increase (1.1 percent) in estimated payments per discharge from FY 2013 to FY 2014. Finally, government-owned and operated LTCHs are also expected to experience an increase in payments of 0.9 percent in estimated payments per discharge from FY 2013 to FY 2014.

(4) Census Region

Estimated payments per discharge for FY 2014 are projected to increase for LTCHs located in all regions in comparison to FY 2013. Of the 9 census regions, we project that the increase in estimated payments per discharge will have the largest positive impact on LTCHs in the Middle Atlantic and Pacific regions (1.6 percent and 1.4 percent, respectively as shown in Table IV). The estimated percent increase in payments per discharge from FY 2013 to FY 2014 for those regions is largely attributable to the proposed changes in the area wage level adjustment or proposed updates to the MS–LTC–DRGs classifications and relative weights.

In contrast, LTCHs located in the South Atlantic and West South Central regions are projected to experience the smallest increase in estimated payments per discharge from FY 2013 to FY 2014. The lower than average estimated increase in payments of 0.9 percent for LTCHs in the South Atlantic and West South Central regions is primarily due to estimated decreases in payments associated with the proposed 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. Most bed size categories are projected to receive either a slightly higher or slightly lower than average increase in estimated payments per discharge from FY 2013 to FY 2014. We project that small LTCHs (0–24 beds) would experience a 0.6 percent increase in payments, mostly due to decreases in the area wage level adjustment, while large LTCHs (200+ beds) would experience a 1.2 percent increase in payments. LTCHs with between 75 and 124 beds are expected to experience an above average increase in payments per discharge from FY 2013 to FY 2014 (1.2 percent).

4. Effect on the Medicare Program

As noted previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately $62 million (or approximately 1.1 percent) for the 423 LTCHs in our database. In addition, the effects of the expiration of the regulatory moratorium on the application of the ''25-percent threshold'' payment adjustment policy effective for cost reporting periods beginning or after October 1, 2013 (as discussed in section VIII.D. of the preamble of this proposed rule) would result in a payment reduction of approximately $190 million to LTCHs.

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 under the LTCH PPS, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

M. Effects of Proposed Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section IX.A. of the preamble of this proposed rule, we discuss our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2016 payment determination. Information is not available to determine the precise number of hospitals that would not meet the requirements to receive the full annual percentage increase for the FY 2016 payment determination. We now estimate that approximately 200 hospitals may not receive the full annual percentage increase in any fiscal year. Based on historical information, we believe that increased reporting requirements for several new measure topics may contribute to an increase in the number of providers subject to payment reduction. However, historical information also indicates that reporting improves in subsequent years following an initial increase in the number of providers subject to payment reduction. We believe that this reporting improvement will offset increased proposed reporting requirements from newly added measures. Based on our current successful participation rate, we anticipate an increase in the number of hospitals that may not receive the full annual percentage increase—from approximately 95 to approximately 200. At the time that the analysis was prepared, 66 hospitals did not receive the full annual percentage increase for the FY 2013 payment determination.

We estimate that the total burden associated with the voluntary electronic quality measure reporting option will be similar to the burden outlined for hospitals in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 53968 through 54162). However, by allowing hospitals to submit data that could be used to satisfy the requirements for both programs, each hospital that participates in the proposed voluntary electronic quality measure reporting option could realize a reduction in burden of approximately 800 hours. This estimate assumes an annual collection burden for chart abstracted Stroke, VTE and PC–01 to be a combined 816 hours annually per hospital and an estimated 2.66 hours to submit those measures electronically for one quarter. Since the ED measures are a subset of the global measure set that also includes the Immunization measures, which will continue to be collected via chart abstraction, we do not believe there will be a significant reduction in burden for electronic submission of the ED–1 and ED–2 measures.

If our proposals related to validation, including submission of and reimbursement for secure electronic versions of medical information for validation for the FY 2016 payment determination and subsequent years are finalized, as described in the ICRs for the Hospital IQR Program, it will result in a cost savings to CMS of approximately $1.3 million.

The cost to the Federal Government associated with the collection and validation of the data are estimated at $14,550,000.00 annually for the validation, and quality reporting support contracts. In addition, this program takes 3 CMS staff at a GS–13 level to operate. A GS–13 level approximate annual salary is $92,001 for an additional cost of $276,000.

N. Effects of Proposals for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for FY 2014

In section IX.B. of the preamble of this proposed rule, we discuss our proposed policies for FYs 2015 and 2016 for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the 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. The quality reporting requirements affect all PCHs participating in Medicare. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we adopted five quality measures for the FY 2014 program and subsequent program years.

In this proposed rule, we are proposing that PCHs submit data on 1 additional measure beginning with the FY 2015 program and 13 additional measures beginning with the FY 2016 program, for a total of 19 measures. We are not proposing to make changes to the reporting requirements that

we have previously finalized for the five measures we first adopted beginning with the FY 2014 program.

The anticipated burden to these PCHs consists of the following: Training of appropriate staff members on how to use the NSHN for the reporting of the proposed SSI measure, CMS (QualityNet) for the reporting of the proposed SCIP measures, and the CMS Web Measures Tool for the reporting of the proposed clinical process/oncology care measures; the time required for collection and aggregation of data; and the time required for the reporting of data by the PCH's representative.

In addition, in order for a PCH to participate in the collection of HCAHPS data, a PCH must either: (1) Contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the PCH's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a vendor, provided that the PCH attends HCAHPS training. Finally, all PCHS that do not already report data under the PCHQR Program will need to register with QualityNet, identify a QualityNet administrator, complete an online Notice of Participation form, and learn the CMS contractor's and the CDC's collection mechanism in order to submit data for those measures.

One of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be displayed publicly and used to further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use their health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

We will share the information collected under the PCHQR Program with the public as is required under the statute. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a public user-friendly and relevant format, include, but are not limited to: (1) Keeping the public informed of the quality of care that is being provided in PCHs as a whole; (2) keeping the public informed of the quality of care being provided in specific PCHs; (3) allowing the public to compare and contrast the data about specific PCHs, thus enabling the public to make informed health care decisions regarding PCHs; and (4) providing information about current trends in health care. There are many other public uses for these quality data concerning PCHs. Further, keeping the public informed of quality of care provided in health care has always been of high priority to CMS.

We also seek to align the PCHQR Program measures and reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

O. Effects of Proposals for FY 2014 Relating to the LTCH Quality Reporting (LTCHQR) Program

In section IX.C. of the preamble of this proposed rule, we discuss the implementation of section 3004(a) of the Affordable Care Act, which added section 1886(m)(5) to the 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) of the Act will receive a 2.0 percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year. The initial requirements for this LTCHQR Program were finalized in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51839 through 51840), we estimated that only a few LTCHs would not receive the full payment update in any fiscal year because they did not submit data under the LTCHQR Program. Data collection for the LTCHQR Program did not begin until October 1, 2012. We believe that the statements we made in the FY 2012 IPPS/LTCH PPS final rule regarding the number and types of LTCHs that may not receive the full payment update as a result of failing to submit data to the Secretary under the LTCHQR Program remain valid. We are now able to verify, following the first quarter (October 1, 2012-December 31, 2012) of data collection and submission for the LTCHQR Program, that a majority of CMS-certified LTCHs are submitting quality data to CMS. We believe this number will only increase between the date of publication of this proposed rule and the final deadline for the first quarter of data submission (October 1, 2012—December 31, 2012) of May 15, 2013. We believe that a majority of LTCHs will continue to submit data for CY 2013 and sunsequent years because they will continue to view the LTCHQR Program as an important step in improving the quality of care patients receive in the LTCHs.

As discussed in section VIII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule, for FY 2015, we retained the three quality measures that were finalized for use in the LTCHQR Program in the FY 2012 IPPS/LTCH PPS final rule, with some modifications . These measures are: (1) NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138); (2) NHSN Central Line Catheter-Associated Blood Stream Infection Event (CLABSI) Outcome Measure (NQF #0139); and (3) an Application of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51780 through 51781), we estimated that the total yearly cost to all LTCHs that are paid under the LTCH PPS to report these data (including NHSN registration and training for the CAUTI and CLABSI quality measures, data submission for all three measures, and monitoring data submission) will be approximately $756,326. We adopted this same burden estimate in the FY 2013 IPPS/LTCH PPS final rule.

As part of its endorsement maintenance process under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures that we adopted in the FY 2012 IPPS/LTCH PPS final rule. As a result of this review, the NQF expanded the scope of endorsement of these measures to include additional care settings, including LTCHs. In the FY 2013 IPPS/LTCH PPS final rule, we specified that the CAUTI and CLABSI measures will be adopted in their expanded form for the FY 2014 payment update determination and all subsequent fiscal year payment determinations.

We did not believe that the total burden estimate of $756,326 that we made in the FY 2012 IPPS/LTCH PPS final rule would be affected by the expansion of the CAUTI and CLABSI measures. We made this statement because these expanded measures are the same measures we adopted in the FY 2012 IPPS/LTCH PPS final rule, except that the measure names have been changed and the scope of endorsement expanded so as to be applicable to the LTCH setting. The expanded CAUTI and CLABSI measures make no changes to the way that data are to be collected and reported by LTCHs. Thus, the use of the expanded CAUTI and CLABSI measures will place no additional financial burden on LTCHs. In addition, we believe that this financial burden should remain relatively stable over the first several years of this LTCHQR Program, subject to normal inflationary increases, such as increased labor wage rates.

As discussed in section VIII.D.3.d. of the preamble of the FY 2013 IPPS/LTCH PPS final rule, for the FY 2016 LTCHQR Program, we added two additional quality measures to the LTCHQR Program. These quality measures are: (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). Data for the staff immunization measure will be reported by LTCHs to the CDC's NHSN. Details related to the use of NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at *http://www.cdc.gov/nhsn/LTACH/hcp-flu-vac/index.html*.

Data for the patient influenza vaccination measure will be collected using the LTCH CARE Data Set, and we anticipate the new data item set will consist of 3 additional items added to the LTCH CARE Data Set. These items are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0.[195] The LTCH CARE Data Set Version 2.01 is currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction

[195] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.*

Act (PRA).[196] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. The specifications and data elements for this measure are available in the MDS 3.0 QM User's Manual available on our Web site at: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf*.

Because the LTCHQR Program is nearing the end of the submission timeframe first quarter of reporting, we have become more familiar with the burden of this program. We have now received feedback from LTCH providers about the time burden associated with the completion of the LTCH CARE Data Set. We have considered feedback from LTCH providers in the form of public comments to the most recent LTCH proposed rule (FY 2013 IPPS/LTCH PPS proposed rule), questions during Open Door forums, and LTCH helpdesk inquiries. LTCH providers have stated that we had underestimated the amount of time that is required of the LTCH staff to complete the LTCH CARE Data Set on each LTCH patient.

In response to the feedback received, we have significantly revised our burden estimates. For example, in our previous PRA package burden estimate we estimated burden based solely on LTCH yearly discharges of Medicare beneficiaries, while the revised burden estimate includes yearly LTCH discharges of both Medicare and non-Medicare patients. Additionally, the original burden calculation only took one assessment per patient (admission) into account, while the revised estimate includes two assessment records per patient (admission and discharge).

While the burden calculation for this PRA submission has increased significantly compared to our original calculation, we believe that the calculation now more accurately reflects the burden associated with implementing collection of the quality measures, as mandated by section 1886(m)(5) of the Act. For a complete discussion on the current LTCH CARE Data Set version 2.01 burden estimate, we refer readers to the PRA package currently under review by OMB.[197]

In section IX.C.8.b. and c. of the preamble to this proposed rule, we are proposing to adopt four new quality measures for inclusion in the LTCHQR Program: (1) NHSN Facility-Wide Inpatient Hospital-Onset *Methicillin*-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium Difficile* (*C. Difficile*) Outcome Measure (NQF #1717); (3) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals; and (4) Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) The first three proposed measures would apply to the FY 2017 payment update determination and subsequent payment determinations. The fourth proposed measure would apply to the FY 2018 payment update determination and subsequent payment determinations.

Of the measures listed above, we believe that the first two measures (NHSN Facility-Wide Inpatient Hospital-Onset *Methicillin*-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium Difficile* (*C. Difficile*) Outcome Measure (NQF #1717)) will only minimally increase burden on LTCHs. These two measures are reported through the CDC's NHSN. LTCHs will be familiar with the submission of quality data using this system as they began submitting required quality data through NHSN beginning October 1, 2012 for CAUTI and CLABSI measures. The third measure (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals) is a claims-based measure, and it will not increase the reporting burden of LTCHs since it is a Medicare FFS claims-based measure. Lastly, we believe the fourth measure (application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) will also have a minimal impact on the reporting burden as calculated for the LTCH CARE Data Set version 2.01 currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA).[198] This measure will be collected using the LTCH CARE Data Set to which a total of two questions will be added in order to allow CMS to collect the data necessary to calculate this measure.

P. Effects of Proposed Changes to the Requirements for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53644), we finalized policies to implement the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program. One goal of the IPFQR Program is to implement the statutory requirements of section 1886(s)(4) of the Act, as added by sections 3401(f) and 10322(a) of the Affordable Care Act. In addition, one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use such health care quality data for many purposes such as in their risk management programs, patient safety and quality improvement initiatives and research and development of mental health programs, among others.

In section IX.D. of the preamble of this proposed rule, we are proposing that, for the FY 2016 payment determination and subsequent years, IPFs must submit aggregate data on three additional measures, for a total of 9 measures. In addition, we are proposing a request for voluntary information. We are not proposing to make changes to the administrative, reporting or submission requirements for the existing six measures previously finalized in last year's rule (77 FR 53654 through 53657). However, there will be new reporting and submission requirements associated with the three proposed additional measures and proposed request for voluntary information for the FY 2016 payment determination and subsequent years.

We have estimated the burden associated with IPFs complying with the requirements of the IPFQR Program. In our burden estimate calculation, we have included the time that would be spent for (1) the submission of the voluntary information, (2) chart abstractions, and (3) training personnel on the collection of chart-abstracted data, aggregation of the data, and protocols to submit aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures, including 30 minutes needed for the voluntary submission, is approximately 1,030 hours a year for each IPF. Thus, the average hourly burden to each IPF is approximately 86 hours per month. At this time, we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the aggregate impact.

II. Alternatives Considered

This proposed rule contains a range of proposed policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

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 proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall decrease of 0.1 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that proposed operating payments will

[196] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*.

[197] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*.

[198] The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html*.

decrease by approximately $110 million in FY 2014 relative to FY 2013. 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 proposal discussed in section V.E. of the preamble of this proposed rule, we estimate that proposed operating payments would increase by approximately $217 million relative to FY 2013. In addition, we estimate a savings of $26 million associated with the proposed HACs policies in FY 2014, which is an additional $2 million in savings as compared to FY 2013. We estimate that the expiration of the expansion of low-volume hospital payments in FY 2014 under section 605 of the ATRA will result in a decrease in payments of approximately $288 million. We estimate new technology payments will increase payments by $45 million in FY 2014, which is $1 million less than our estimate of new technology payments made in FY 2013. These estimates, combined with our proposed FY 2014 operating estimate of $217 million, result in an estimated decrease of approximately $74 million for FY 2014. We estimate that hospitals will experience a 1.1 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 $101 million increase in capital payments in FY 2014 compared to FY 2013. The proposed cumulative operating and capital payments would result in a net increase of approximately $27 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2014. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including proposed updated wage index values and relative weights, and the best available claims and CCR data to estimate the proposed change in payments under the LTCH PPS for FY 2014. Accordingly, based on the best available data for the 423 LTCHs in our database, we estimate that FY 2014 LTCH PPS payments will increase approximately $62 million relative to FY 2013 as a result of the proposed payment rates and factors presented in this proposed rule. In addition, we estimate that the expiration of the moratorium on the full application of the ''25-percent threshold'' payment adjustment policy under current law, beginning with cost reporting period beginning on or after October 1, 2013 as discussed in section VIII.D. of the preamble of this proposed rule, will result in a reduction in LTCH PPS payments of $190 million.

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 proposed rule as they relate to acute care hospitals. This table provides our best estimate of the proposed change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The cost to the Federal Government associated with the policies in this proposed rule are estimated at $27 million.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2013 TO FY 2014

Category	Transfers
Annualized Monetized Transfers.	$27 million.
From Whom to Whom	Federal Government to IPPS Medicare Providers.
Total	$27 million.

B. LTCHs

As discussed in section I.L. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS, in conjunction with the estimated payment impact of the moratorium on the full application of the ''25-percent threshold'' payment adjustment policy under current law, is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately −$128 million based on the data for 423 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 proposed rule as they relate to the proposed changes to the LTCH PPS. Table VI provides our best estimate of the estimated decrease in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 423 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 proposed policies for LTCHs in this proposed rule is estimated at $128 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES FROM THE FY 2013 LTCH PPS TO THE FY 2014 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	Negative transfer—Estimated decrease in expenditures: $128 million.

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 $34.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/contractingopportunities/sizestandardtopics/tableofsize/index.html.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals 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.L. of this Appendix. Medicare fiscal intermediaries and 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 proposed rule constitutes our regulatory flexibility analysis. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we receive and our responses will be presented in the 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 proposed 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 2013, that threshold level is approximately $141 million. This proposed 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 proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, 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 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 2014, 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 2014

A. Proposed FY 2014 Inpatient Hospital Update

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2014 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of 2.0 percentage points if the hospital fails to submit quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.3 percentage point. 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 the application of the multifactor productivity adjustment and the additional FY 2014 adjustment of 0.3 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace the FY 2006-based IPPS operating and capital market baskets with revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section V.A.1. of the preamble of this proposed rule, we are proposing a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2014) of 0.4 percent. Therefore, based on IHS Global Insight Inc.'s (IGI's) first quarter 2013 forecast of the proposed FY 2010-based IPPS market basket, we are proposing an applicable percentage increase to the FY 2013 operating standardized amount of 1.8 percent (that is, the proposed FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(viii) of the Act and our rules. For hospitals that fail to submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of −0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.4 percentage point for economy-wide productivity, and less an additional adjustment of 0.3 percentage point).

B. Proposed Update for SCHs for FY 2014

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2014 applicable percentage increase in the hospital-specific rate for SCHs 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 rate for SCHs 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, we are proposing an applicable percentage increase to the hospital-specific rate applicable to SCHs of 1.8 percent for hospitals that submit quality data or −0.2 percent for hospitals that fail to submit quality data.

C. Proposed FY 2014 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 proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.8 percent.

D. Proposed Update for Hospitals Excluded From the IPPS

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 and cancer hospitals. 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, and RNHCIs are among the remaining three types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. We are proposing that, for FY 2014 and subsequent fiscal years, the rate-of-increase percentage applicable to the target amount for children's hospitals, PPS-excluded cancer hospitals, and RNHCIs is the percentage increase in the proposed revised and rebased FY 2010-based IPPS operating market basket. Accordingly, the FY 2014 rate-of-increase percentage to be applied to the target amount for cancer hospitals, children's hospitals, and RNHCIs would be the FY 2014 percentage increase in the proposed revised and rebased FY 2010-based IPPS operating market basket. For this proposed rule, the current estimate of the FY 2014 IPPS operating market basket percentage increase is 2.5 percent.

E. Proposed Update for LTCHs for FY 2014

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to establish an update to the LTCH

PPS standard Federal rate for FY 2014 based on the full LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 2.5 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)(D) of the Act, provided the LTCH submits quality data in accordance with section 1886(m)(5)(C) of the act and our rules. Beginning in FY 2014, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit quality data. The productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.4 percent for FY 2014. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2014 be reduced by the ''other adjustment'' at section 1886(m)(4)(D) of the Act, which is 0.3 percentage point. Therefore, based on IGI's first quarter 2013 forecast of the FY 2014 market basket increase, we are proposing an annual update to the LTCH PPS standard Federal rate of 1.8 percent (that is, the current FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point), provided the LTCH submits quality data in accordance with the LTCHQR Program under section 1886(m)(5)(C) of the Act. Accordingly, we are proposing to apply an update factor of 1.018 in determining the LTCH PPS standard Federal rate for FY 2014 provided the LTCH submits quality data in accordance with section 1886(m)(5)(C) of the Act and our rules. For LTCHs that fail to submit quality data, we are proposing an annual update to the LTCH PPS standard Federal rate of −0.2 percent (that is, the FY 2014 estimate of the market basket rate-of increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity, less an additional adjustment of 0.3 percentage point, and less 2.0 percentage points for failure to submit quality data) by applying an update factor of 0.998 in determining the LTCH PPS standard Federal rate for FY 2014. Furthermore, we are proposing to make an adjustment for the second year of the 3-year phase-in of the one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) by applying a factor of 0.98734 (or approximately −1.3 percent) in FY 2014, consistent with current law.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2014. 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, we are recommending an applicable percentage increase to the standardized amount of 1.8 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and the Puerto Rico-specific standardized amount.

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 for children's hospitals, cancer hospitals, and RNHCIs of 2.5 percent.

For FY 2014, consistent with policy set forth in section VIII. of the preamble of this proposed rule, we are recommending an update of 1.8 percent (that is, the current FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point) to the LTCH PPS standard Federal rate.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2013 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 1.0 percent. MedPAC expects Medicare margins to remain low in 2013. 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. MedPAC also recommended that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2014 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 1 percent, for FY 2014, as discussed above, sections 3401(a) and 10319(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act. Section 1886(b)(3)(B) of the Act, as amended by these sections, sets the requirements for the FY 2014 applicable percentage increase. Therefore, we are proposing an applicable percentage increase for FY 2014 of 1.8 percent, provided the hospital submits quality data, consistent with these statutory requirements.

With regard to MedPAC's recommendation that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2014 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes, we refer readers to section II.D. of the preamble of this proposed rule for a complete discussion of the FY 2014 documentation and coding adjustment. We note that section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment totaling $11 billion by 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. Our actuaries estimate that if CMS were to fully account for the $11 billion recoupment required by section 631 of the ATRA in FY 2014, a −9.3 percent adjustment to the standardized amount would be necessary. MedPAC estimates that a −2.4 percent adjustment made in FY 2014, and not removed until FY 2018, also would recover the required recoupment amount. It is often our practice to delay or phase in rate adjustments over more than 1 year, in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we are proposing a −0.8 percent adjustment to the standardized amount in FY 2014.

We also 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 proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

[FR Doc. 2013–10234 Filed 4–26–13; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1449–P]

RIN 0938–AR64

Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the hospice payment rates and the wage index for fiscal year (FY) 2014, and continue the phase out of the wage index budget neutrality adjustment factor (BNAF). Including the FY 2014 15 percent BNAF reduction, the total BNAF reduction in FY 2014 will be 70 percent. The BNAF phase-out will continue with successive 15 percent reductions in FY 2015 and FY 2016. This proposed rule would also clarify how hospices are to report diagnoses on hospice claims, and proposes changes in

the requirements for the hospice quality reporting program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 28, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1449–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1449–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1449–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

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, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously 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, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Debra Dean-Whittaker, (410) 786–0848 for questions regarding the hospice experience of care survey. Robin Dowell, (410) 786–0060 for questions regarding quality reporting for hospices and collection of information requirements. Hillary Loeffler, (410) 786–0456 for general questions about hospice payment. Katherine Lucas, (410) 786–7723 for questions regarding payment reform. Anjana Patel, (410) 786–2120 for questions regarding the hospice wage index and payment rates. Kelly Vontran, (410) 786–0332 for questions on diagnosis reporting on hospice claims.

SUPPLEMENTARY INFORMATION:

Wage Index Addenda: In the past, the wage index addenda referred to in the preamble of our proposed and final rules were available in the **Federal Register**. However, the wage index addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these addenda will be available only through the Internet on the CMS Web site at: (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html*.) Readers who experience any problems accessing any of the wage index addenda related to the hospice payment rules that are posted on the CMS Web site identified above should contact Anjana Patel at 410–786–2120.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following 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.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

APU Annual Payment Update
BBA Balanced Budget Act of 1997
BNAF Budget Neutrality Adjustment Factor
BLS Bureau of Labor Statistics
CAHPS Consumer Assessment of Healthcare Providers and Systems
CBSA Core-Based Statistical Area
CMS Centers for Medicare & Medicaid Services
CCW Chronic Conditions Warehouse
CHC Continuous Home Care
COPD Chronic Obstructive Pulmonary Disease
CoPs Conditions of Participation
CR Change Request
CVA Cerebral Vascular Accident
DME Durable Medical Equipment
FEHC Family Evaluation of Hospice Care
FY Fiscal Year
GIP General Inpatient Care
HIS Hospice Item Set
HHS Health and Human Services
HQRP Hospice Quality Reporting Program
LUPA Low Utilization Payment Amount
MedPAC Medicare Payment Advisory Commission
MFP Multi-factor Productivity
MSA Metropolitan Statistical Area
NEC Not Elsewhere Classified
NPI National Provider Identifier
NQF National Quality Forum
OACT Office of the Actuary
OMB Office of Management and Budget
OIG Office of Inspector General
PRA Paperwork Reduction Act
PRRB Provider Reimbursement Review Board
QAPI Quality Assessment and Performance Improvement
QRP Quality Reporting Program
RFA Regulatory Flexibility Act
RHC Routine Home Care
SBA Small Business Administration
TEFRA Tax Equity and Fiscal Responsibility Act of 1982
TEP Technical Expert Panel

I. Executive Summary for This Proposed Rule

A. Purpose

This rule proposes updates to the payment rates for hospice providers for fiscal year (FY) 2014 as required under section 1814 (i) of the Social Security Act (the Act). The proposed updates incorporate the use of updated hospital wage index data, the 5th year of the 7-year Budget Neutrality Adjustment Factor (BNAF) phase-out, and an update to the hospice payment rates by the hospice payment update percentage. Additionally, this proposed rule clarifies diagnosis reporting on hospice claims, provides an update on hospice payment reform and additional data collection requirements, and proposes changes to the quality reporting requirements for hospice providers.

B. Summary of the Major Provisions

In this rule we propose to update the hospice payment rates for FY 2014 by 1.8 percent as described in section III.C.3. The hospice wage index would be updated with more current wage data and the BNAF will be reduced by an additional 15 percent for a total BNAF reduction of 70 percent as described in section III.C.2. The August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39384) finalized a 10 percent reduced BNAF for FY 2010 as the first year of a 7-year phase-out of the BNAF, to be followed by an additional 15 percent per year reduction in the BNAF in each of the next 6 years. The total BNAF phase-out will be complete by FY 2016. This proposed rule also clarifies diagnosis reporting on hospice claims, especially regarding the use of non-specific symptom diagnoses; provides an update on hospice payment reform and additional data collection requirements; proposes a technical regulations text change; and proposes changes to the hospice quality reporting program.

C. Summary of Costs, Benefits, and Transfers

TABLE 1—TRANSFERS

Provision description	Total
FY 2014 Hospice Payment Rate Update.	The overall economic impact of this proposed rule is an estimated $180 million in increased payments to hospices.

II. Background

A. Hospice Care

Coping with a life-limiting illness can be an overwhelming experience, physically, emotionally and spiritually, for both the person and his or her family. Recognition that the care needs at end-of-life are different from other health care needs is a foundation of the Medicare hospice benefit. Hospice is a compassionate care philosophy and practice for those who are terminally ill. It is a holistic approach to treatment that recognizes that the impending death of an individual warrants a change from curative to palliative care. Palliative care means ''patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3).'' Palliative care is at the core of hospice philosophy and care practices. The person beginning hospice care, or his or her representative, needs to understand that his or her illness is no longer responding to medical interventions to cure or slow the progression of disease and then must choose to stop further curative attempts while palliative care continues and intensifies, as needed, for continued symptom management. As we stated in the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088), palliative care is an approach that ''optimizes quality of life by anticipating, preventing, and treating suffering''. The goal of palliative care in hospice is to improve the quality of life of individuals and their families facing the issues associated with life-threatening illness through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other issues. In addition, palliative care in hospice includes coordinating care services, reducing unnecessary diagnostics or ineffective therapies, and offering ongoing conversations with individuals and their families about changes in the disease and shifts in the plan of care to meet the changing needs with disease progression as the individual approaches the end-of-life.

Medicare hospice care is palliative care for individuals with a prognosis of living 6 months or less if the terminal illness runs its normal course. As generally accepted by the medical community, the term ''terminal illness'' refers to an advanced and progressively deteriorating illness, and the illness is

diagnosed as incurable. When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. In the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088), we stated ''the medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness.'' As referenced in our regulations at 42 CFR 418.22(b)(1), to be eligible for Medicare hospice services, the beneficiary's attending physician (if any) and the hospice medical director must certify that the individual is terminally ill, that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course as defined in section 1861(dd)(3)(A) of the Act and further clarified in § 418.3. The certification of terminal illness must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms as stated in § 418.22(b)(3).

The goal of hospice care is to make the hospice patient as physically and emotionally comfortable as possible, with minimal disruption to normal activities, while remaining primarily in the home environment. Hospice care uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through the use of a broad spectrum of professional and other caregivers and volunteers. While the goal of hospice care is to allow for the individual to remain in his or her home environment, circumstances during the end-of-life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice facility for procedures necessary for pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services are to ensure that any new or worsening symptoms are intensively addressed so that the individual can return to his or her home environment under routine hospice care. Short-term, intermittent, inpatient respite services are also available to the family of the hospice patient when needed to relieve the family or other caregivers. Additionally, an individual can receive continuous home care during a period of crisis in which an individual requires primarily continuous nursing care to achieve palliation or management of acute medical symptoms to maintain the individual at home. Continuous home care may be covered on a continuous basis for as much as 24 hours a day and these periods must be predominantly nursing care per our regulations at § 418.204. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

B. History of the Medicare Hospice Benefit

Before the creation of the Medicare hospice benefit, hospice was originally run by volunteers who cared for the dying. During the early development stages of the Medicare Hospice Benefit, hospice advocates, working with legislators, were clear that they wanted a Medicare benefit available that provided all-inclusive care for terminally-ill individuals, provided pain relief and symptom management, and offered the opportunity to die with dignity in the comfort of one's home rather than in an institutional setting.[1] As stated in the August 22, 1983 proposed rule entitled ''Medicare Program; Hospice Care'' (48 FR 38146), ''the hospice experience in the United States has placed emphasis on home care. It offers physician services, specialized nursing services, and other forms of care in the home to enable the terminally ill individual to remain at home in the company of family and friends as long as possible.'' The concept of a beneficiary ''electing'' the hospice benefit and being certified as terminally ill were two key components put into the legislation responsible for the creation of the Medicare hospice benefit (section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), (Pub. L. 97–248)). Section 122 of TEFRA created the Medicare hospice benefit, which was implemented on November 1, 1983 under section 1861(dd) of the Social Security Act (the Act), codified at 42 U.S.C. 1395x(dd), to provide coverage of hospice care for terminally ill Medicare beneficiaries who elected to receive care from a Medicare-certified, hospice. In § 418.54(c), our regulations stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions which must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors: the nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms. The Medicare hospice benefit requires the hospice to cover all palliative care related to the terminal illness and related conditions. In the December 16, 1983 Hospice final rule, hospices are also to cover care for interventions to manage pain and symptoms (48 FR 56008). Clinically, related conditions are any physical or mental condition(s) that are related to or caused by either the terminal illness or the medications used to manage the terminal illness.[2] Additionally, per the hospice Conditions of Participation at § 418.56, hospice must provide all services necessary for the palliation and management of the terminal illness, related conditions and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort without undue symptom burden for the hospice patient or family.[3] For example, a hospice patient with lung cancer (the terminal illness) may receive inhalants for shortness of breath (related to the terminal condition). The patient may also suffer from metastatic bone pain (a related condition) and would be treated with opioid analgesics. As a result of the opioid therapy, the patient may suffer from constipation (an associated symptom) and requires a laxative for symptom relief. It is often not a single diagnosis that represents the terminal illness of the patient, but the combined effect of several conditions that makes the patient's condition terminal. We are restating what we communicated in the December 16, 1983 Hospice final rule regarding what is related versus unrelated to the terminal illness: ''. . . we believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case–by-case basis. It is our general view that . . . ''hospices are required to provide virtually all the care that is needed by terminally ill patients'' (48 FR 56010 through 56011). Therefore, unless there

[1] Connor, Stephen. (2007). Development of Hospice and Palliative Care in the United States. OMEGA. 56(1), p89–99.

[2] Harder, PharmD, CGP, Julia. (2012). To Cover or Not To Cover: Guidelines for Covered Medications in Hospice Patients. The Clinician. 7(2), p1–3.

[3] Paolini, DO, Charlotte. (2001). Symptoms Management at End of Life. JAOA. 101(10). p609–615.

is clear evidence that a condition is unrelated to the terminal illness, all services would be considered related. It is also the responsibility of the hospice physician to document why a patient's medical need(s) would be unrelated to the terminal illness.

The fundamental premise upon which the hospice benefit was designed was the ''revocation'' of traditional curative care and the ''election'' of hospice care for end-of-life symptom management and maximization of quality of life as stated in the December 16, 1983 Hospice final rule (48 FR 56008). After electing hospice care, the patient typically returns to the home from an institutionalized setting or remains in the home, to be surrounded by family and friends, and to prepare emotionally and spiritually for death while receiving expert symptom management and other supportive services. Election of hospice care also includes waiving curative treatment for the terminal prognosis, and instead receiving palliative care to manage pain or symptoms.

The benefit was originally designed to cover hospice care for a finite period of time that roughly corresponded to a life expectancy of 6 months or less. Initially, beneficiaries could receive three election periods: two 90-day periods and one 30-day period. Currently, Medicare beneficiaries can elect hospice care for two 90-day periods and an unlimited number of subsequent 60-day periods; however, the expectation remains that beneficiaries have a life expectancy of 6 months or less if the terminal illness runs its normal course.

C. Services Covered by the Medicare Hospice Benefit

To be covered under the Medicare hospice benefit, hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program. These covered services include: nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and procedures necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; continuous home care during periods of crisis and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, that hospice program and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (described in section 1861(dd)(2)(B)) of the Act.

The services offered under the hospice benefit must be available, as needed, to beneficiaries 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act). Upon the implementation of the hospice benefit, the Congress expected hospices to continue to use volunteer services, though these services are not to be reimbursed. The hospice interdisciplinary group should be comprised of paid hospice employees as well as hospice volunteers, as stated in the August 22, 1983 Hospice proposed rule (48 FR 38149). This expectation is in line with the history of hospice and philosophy of holistic, comprehensive, compassionate, end-of-life care.

The National Hospice Study was initiated in 1980 through a grant sponsored by the Robert Wood Johnson and John A. Hartford Foundations and CMS (formerly, the Health Care Financing Administration (HCFA). The study was conducted between October 1980 and March 1983. The study summarized the hospice care philosophy as the following:

- Patient and family know of the terminal condition.
- Further medical treatment and intervention are indicated only on a supportive basis.
- Pain control should be available to patients as needed to prevent rather than to just ameliorate pain.
- Interdisciplinary teamwork is essential in caring for patient and family.
- Family members and friends should be active in providing support during the death and bereavement process.
- Trained volunteers should provide additional support as needed.

In the August 22, 1983 Hospice proposed rule (48 FR 38149) we stated ''the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices''.

D. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in 42 CFR part 418, establish eligibility requirements, payment standards and procedures, define covered services, and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (routine home care, continuous home care, inpatient respite care, and general inpatient care) to hospices, based on each day a qualified Medicare beneficiary is under hospice election. This per diem payment is to include all of the services needed to manage the beneficiaries' care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today with some adjustments, as noted below:

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L 101–239) amended section 1814(i)(1)(C) of the Act and provided for the following two changes in the methodology concerning updating the daily payment rates: (1) effective January 1, 1990, the daily payment rates for routine home care and other services in included in hospice care were increased to equal 120 percent of the rates in effect on September 30, 1989; and (2) the daily payment rate for routine home care and other services included in hospice care for fiscal years beginning on or after October 1, 1990, were the payment rates in effect during the previous Federal fiscal year increased by the hospital market basket percentage increase.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L 105–33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002 Hospice rates were updated by a factor equal to the hospital market basket percentage increase, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent fiscal years will be the hospital market basket percentage increase for the FY. The Social Security

Act requires us to use the inpatient hospital market basket to determine hospice payment rates.

3. Hospice Wage Index Final Rule for FY 1998

In the August 8, 1997 FY 1998 Hospice Wage Index final rule (62 FR 42860), we implemented a new methodology for calculating the hospice wage index based on the recommendations of a negotiated rulemaking committee. The original hospice wage index was based on 1981 Bureau of Labor Statistics hospital data and had not been updated since 1983. In 1994, because of disparity in wages from one geographical location to another, the Hospice Wage Index Negotiated Rulemaking Committee was formed to negotiate a new wage index methodology that could be accepted by the industry and the government. This Committee was comprised of representatives from national hospice associations; rural, urban, large and small hospices, and multi-site hospices; consumer groups; and a government representative. The Committee decided that in updating the hospice wage index, aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index, to cushion the impact of using a new wage index methodology. To implement this policy, a Budget Neutrality Adjustment Factor (BNAF) would be computed and applied annually to the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index, subject to a wage index floor.

4. Hospice Wage Index Final Rule for FY 2010

Inpatient hospital pre-floor and pre-reclassified wage index values, as described in the 1997 Hospice Wage Index final rule are subject to either a budget neutrality adjustment or application of the wage index floor. Wage index values of 0.8 or greater are adjusted by the budget neutrality adjustment factor (BNAF). Starting in FY 2010, a 7-year phase-out of the BNAF began (August 6, 2009 FY 2010 Hospice Wage Index final rule, 74 FR 39384), with a 10 percent reduction in FY 2010, and additional 15 percent reduction for a total of 25 percent in FY 2011, an additional 15 percent reduction for a total 40 percent in FY 2012, and an additional 15 percent reduction for a total of 55 percent in FY 2013. The phase-out will continue with an additional 15 percent reduction for a total reduction of 70 percent in FY 2014, an additional 15 percent reduction for a total reduction of 85 percent in FY 2015, and an additional 15 percent reduction for complete elimination in FY 2016. Note that the BNAF is an adjustment which increases the hospice wage index value. Therefore the BNAF reduction is a reduction in the amount of the BNAF increase applied to the hospice wage index value. It is not a reduction in the hospice wage index value, or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent fiscal years), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act will be annually reduced by changes in economy-wide productivity, as specified in section 1886(b)(3)(B)(xi)(II) of the Act, as amended by section 3132(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L 111–152) (the Affordable Care Act)). In FY 2013 through FY 2019, the market basket percentage update under the hospice payment system will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions as specified in section 1814(i)(1)(C)(v) of the Act).

In addition, sections 1814(i)(5)(A) through (C) of the Act, as amended by section 3132(a) of the Affordable Care Act, require hospices to begin submitting quality data, based on measures to be specified by the Secretary, for FY 2014 and subsequent fiscal years. Beginning in FY 2014, hospices which fail to report quality data will have their market basket update reduced by 2 percentage points.

Section 1814(a)(7)(D)(i) of the Act was amended by section 3132 (b)(2)(D)(i) of the Affordable Care Act, and requires, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with an individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification and attest that such visit took place. When implementing this provision, we decided that the 180th-day recertification and subsequent recertifications corresponded to the recertification for a beneficiary's third or subsequent benefit periods (August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47314)).

Further, section 1814(i) of the Act, as amended by section 3132(a) of the Affordable Care Act, authorizes the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the Affordable Care Act would capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determines to be appropriate. The data collected may be used to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we are required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. Hospice Wage Index Final Rule for FY 2012

When the Medicare hospice benefit was implemented, the Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice provider can receive in a year. The Congress stipulated that a ''cap amount'' be computed each year. The cap amount was set at $6,500 per beneficiary when first enacted in 1983 and is adjusted annually by the change in the medical care expenditure category of the consumer price index for urban consumers from March 1984 to March of the cap year (section 1814(i)(2)(B) of the Act). The cap year is defined as the period from November 1st to October 31st. As we stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314), for the 2012 cap year and subsequent cap years, the hospice aggregate cap will be calculated using the patient-by-patient proportional methodology, within certain limits. We will allow existing hospices the option of having their cap calculated via the original streamlined methodology, also within certain limits. New hospices will have their cap determinations calculated using the patient-by-patient proportional methodology. The patient-by-patient proportional methodology and the streamlined methodology are two different methodologies for counting beneficiaries when calculating the hospice aggregate cap. A detailed explanation of these methods is found in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314). If a hospice's total Medicare reimbursement for the cap year exceeded the hospice aggregate

cap, then the hospice would have to repay the excess back to Medicare.

E. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, and especially within the last decade, there has been substantial growth in hospice utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.3 million in FY 2012. Similarly, Medicare hospice expenditures have risen from $2.9 billion in FY 2000 to $14.7 billion in FY 2012. Our Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase by approximately 8 percent annually, reflecting an increase in the number of Medicare beneficiaries, more beneficiary awareness of the Medicare hospice benefit for end-of-life care, and a growing preference for care provided in home and community-based settings. However, this increased spending is partly due to an increased average lifetime length of stay for beneficiaries, from 54 days in 2000 to 86 days in FY 2010, an increase of 59 percent.

There have also been noted changes in the diagnosis patterns among Medicare hospice enrollees, with a growing percentage of beneficiaries with non-cancer diagnoses. Specifically, there were notable increases between 2002 and 2007 in neurologically-based diagnoses, including various dementia diagnoses. Additionally, there have been significant increases in the use of non-specific, symptom-classified diagnoses, such as ''debility'' and ''adult failure to thrive.'' In FY 2012, both ''debility'' and ''adult failure to thrive'' were in the top five claims-reported hospice diagnoses and were the first and third most common hospice diagnoses, respectively (see table 2 below).

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2012

Rank	ICD–9/Reported Principal Diagnosis	Total patients	Percentage
	Year: 2002 Total Patients = 663,406		
1	162.9 Lung Cancer	73,769	11
2	428.0 Congestive Heart Failure	45,951	7
3	799.3 Debility Unspecified	36,999	6
4	496 COPD	35,197	5
5	331.0 Alzheimer's Disease	28,787	4
6	436 CVA/Stroke	26,897	4
7	185 Prostate Cancer	20,262	3
8	783.7 Adult Failure To Thrive	18,304	3
9	174.9 Breast Cancer	17,812	3
10	290.0 Senile Dementia, Uncomp.	16,999	3
11	153.0 Colon Cancer	16,379	2
12	157.9 Pancreatic Cancer	15,427	2
13	294.8 Organic Brain Synd Nec	10,394	2
14	429.9 Heart Disease Unspecified	10,332	2
15	154.0 Rectosigmoid Colon Cancer	8,956	1
16	332.0 Parkinson's Disease	8,865	1
17	586 Renal Failure Unspecified	8,764	1
18	585 Chronic Renal Failure (End 2005)	8,599	1
19	183.0 Ovarian Cancer	7,432	1
20	188.9 Bladder Cancer	6,916	1
	Year: 2007 Total Patients = 1,039,099		
1	799.3 Debility Unspecified	90,150	9
2	162.9 Lung Cancer	86,954	8
3	428.0 Congestive Heart Failure	77,836	7
4	496 COPD	60,815	6
5	783.7 Adult Failure To Thrive	58,303	6
6	331.0 Alzheimer's Disease	58,200	6
7	290.0 Senile Dementia Uncomp.	37,667	4
8	436 CVA/Stroke	31,800	3
9	429.9 Heart Disease Unspecified	22,170	2
10	185 Prostate Cancer	22,086	2
11	174.9 Breast Cancer	20,378	2
12	157.9 Pancreas Unspecified	19,082	2
13	153.9 Colon Cancer	19,080	2
14	294.8 Organic Brain Syndrome NEC	17,697	2
15	332.0 Parkinson's Disease	16,524	2
16	294.10 Dementia In Other Diseases w/o Behav. Dist.	15,777	2
17	586 Renal Failure Unspecified	12,188	1
18	585.6 End Stage Renal Disease	11,196	1
19	188.9 Bladder Cancer	8,806	1
20	183.0 Ovarian Cancer	8,434	1
	Year: 2012 Total Patients = 1,328,651		
1	799.3 Debility Unspecified	161,163	12
2	162.9 Lung Cancer	89,636	7
3	783.7 Adult Failure To Thrive	86,467	7
4	428.0 Congestive Heart Failure	84,333	6
5	496 COPD	74,786	6

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2012—Continued

Rank	ICD–9/Reported Principal Diagnosis	Total patients	Percentage
6	331.0 Alzheimer's Disease	64,199	5
7	290.0 Senile Dementia, Uncomp.	56,234	4
8	429.9 Heart Disease Unspecified	32,081	2
9	436 CVA/Stroke	31,987	2
10	294.10 Dementia In Other Diseases w/o Behavioral Dist.	27,417	2
11	174.9 Breast Cancer	22,421	2
12	153.9 Colon Cancer	22,197	2
13	157.9 Pancreatic Cancer	22,007	2
14	332.0 Parkinson's Disease	21,183	2
15	185 Prostate Cancer	21,042	2
16	294.8 Other Persistent Mental Dis.-classified elsewhere	17,762	1
17	585.6 End Stage Renal Disease	17,545	1
18	518.81 Respiratory Failure	12,962	1
19	294.11 Dementia In Other Diseases w/Behavioral Dist	11,751	1
20	188.9 Bladder Cancer	10,511	1

Source: FY 2002, 2007, and 2012 hospice claims data from the Chronic Condition Warehouse (CCW), accessed on February 14 and February 20, 2013.

Note(s): The frequencies shown represent beneficiaries that had a least one claim with the specific ICD–9 code listed as the principal diagnosis. Beneficiaries could be represented multiple times in the results if they have multiple claims during that time period with different principal diagnoses.

III. Provisions of the Proposed Rule

A. Diagnosis Reporting on Hospice Claims

This section is a clarification of existing ICD–9–CM coding guidelines. No proposals are being made in this proposed rule with regards to diagnosis coding. These clarifications are not intended to preclude any clinical judgment in determining a beneficiary's eligibility for hospice services, rather these clarifications are to address current and ongoing diagnosis reporting patterns noted on hospice claims. A beneficiary who elects hospice care and meets our eligibility requirements at § 418.20, is admitted to the hospice and receives hospice care *prior* to any claim submission, which occurs at the end of each calendar month while under hospice services, or upon the death or discharge of the beneficiary, whichever occurs first. In the July 27, 2012 FY 2013 Hospice Wage Index notice (77 FR 44247), we provided in-depth information regarding longstanding, existing ICD–9–CM coding guidelines. We also discussed related versus unrelated diagnosis reporting on claims and clarified that ''all of a patient's coexisting or additional diagnoses'' related to the terminal illness or related conditions should be reported on the hospice claims. Based on analysis of preliminary claims data from the first quarter of FY 2013 (October 1, 2012 through December 31, 2012), 72 percent of providers still only report one diagnosis on the hospice claim. This hospice diagnosis data is comparable to the hospice diagnosis data reported in the July 27, 2012 FY 2013 Hospice Wage Index notice (77 FR 44242), in which we stated that over 77 percent of the hospice claims reported only a principal diagnosis. Therefore, in this year's proposed rule, we are further clarifying the ICD–9–CM coding guidelines and CMS' expectations for diagnosis reporting on the hospice claims in order to ensure the Medicare hospice beneficiaries are receiving the holistic comprehensive hospice services based on the initial and ongoing comprehensive assessment and the individualized hospice plan of care. Eligibility for hospice services is based on meeting the eligibility requirements as stated in § 418.20 of our regulations. For beneficiaries eligible for the Medicare hospice benefit, access to hospice care or the continuation of hospice care should not be affected or limited by the following ICD–9–CM coding guidelines for diagnosis reporting on claims.

1. ICD–9–CM Coding Guidelines

As previously reported in Section II.E of this proposed rule there have been noted changes in reported hospice diagnosis patterns with the top reported hospice diagnoses being non-cancer diagnoses. The hospice benefit covers all care for the terminal illness, related conditions, and for the management of pain and symptoms. As noted in the *ICD–9–CM Official Guidelines for Coding and Reporting,* effective October 1, 2011, available at the CMS Web site at the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/ICD9ProviderDiagnosticCodes/* or on the CDC's Web site at: *http://www.cdc.gov/nchs/data/icd9/icd9cm_guidelines_2011.pdf,* ''these coding and reporting guidelines are a set of rules that have been developed to accompany and complement the official conventions and instructions provided with the ICD–9–CM itself. Adherence to these guidelines when assigning ICD–9–CM diagnosis and procedure codes is required under the Health Insurance Portability and Accountability Act (HIPAA).''

Additionally, in our regulations at 45 CFR 162.1002, the Secretary adopted the ICD–9–CM code set, including The Official ICD–9–CM Guidelines for Coding and Reporting. The CMS' Hospice Claims Processing manual (Pub 100–04, chapter 11) requires that hospice claims include other diagnoses ''as required by ICD–9–CM Coding Guidelines'' available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c11.pdf.* HIPAA, federal regulations, and the Medicare hospice claims processing manual all require that these ICD–9–CM Coding Guidelines be applied to the coding and reporting of diagnoses on hospice claims. Regarding diagnosis reporting on hospice claims, we clarified in our July 27, 2012 FY 2013 Hospice Wage Index notice (77 FR 44247 through 44248) that all providers should code and report the principal diagnosis as well as all coexisting and additional diagnoses related to the terminal condition or related conditions to more fully describe the Medicare patients they are treating.

We are actively collecting and analyzing hospice data for evaluation of hospice payment reform methodologies as mandated in section 3132(a) of the Affordable Care Act. To adequately account for any clinical complexities a given hospice patient might have as a result of related conditions, these related conditions must be included on

the Medicare hospice claim. Some hospice providers already report related additional and coexisting diagnoses on their claims; however, the majority of hospice providers do not report this information. The reporting of only one principal diagnosis does not lend to a comprehensive, holistic, and accurate description of the beneficiaries' end-of-life conditions and may not fully reflect the individualized needs in the individual's required hospice plan of care. As a result, analysis of current claims data does not allow us to appropriately determine whether case-mix adjustment, or other considered methods would or would not be a reasonable approach to, or part of, hospice payment reform. Ongoing hospice data analysis is available on the CMS Hospice Center Web page at: *http://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

2. Use of Nonspecific, Symptom Diagnoses

As mentioned in section II.E, of this proposed rule, there have been changes in the reported hospice principal diagnoses since the inception of the Medicare hospice benefit. In 1983, the most common reported hospice diagnoses were cancer diagnoses. Over time, and with the advancements in medical technology and interventions, there has been a notable shift in the most commonly reported hospice diagnoses from cancers to non-cancer terminal illnesses, such as ''debility'' and ''adult failure to thrive,'' which are considered to be nonspecific, symptom diagnoses according to ICD–9–CM Coding Guidelines and are under the ICD–9–CM classification of ''Symptoms, Signs and Ill-defined Conditions''.

Codes under the classification, ''Symptoms, Signs, and Ill-defined Conditions'', are not to be used as principal diagnosis when a related definitive diagnosis has been established or confirmed by the provider. ''Debility'' is medically defined as: an unspecified syndrome characterized by unexplained weight loss, malnutrition, functional decline, multiple chronic conditions contributing to the terminal progression, and increasing frequency of outpatient visits, emergency department visits and/or hospitalizations. ''Debility'' is associated with multiple primary conditions. The individual diagnosed with ''Debility'' may have multiple comorbid conditions that individually, may not deem the individual to be terminally ill. However, the collective presence of these multiple comorbid conditions will contribute to the terminal status of the individual. Data analysis using FY 2012 claims data for those beneficiaries with a reported principal hospice diagnosis of ''debility,'' and reported secondary diagnoses, shows that congestive heart failure, coronary artery disease, heart disease, atrial fibrillation, Parkinson's disease, Alzheimer's disease, renal failure, chronic kidney disease, and chronic obstructive pulmonary disease are among the most common secondary diagnoses reported. ''Adult Failure to Thrive'' is often used interchangeably with ''Debility'' as a primary hospice diagnosis. Despite the specificity of ICD–9–CM Coding Guidelines, it is unclear as to why these two diagnoses are often used interchangeably. ''Adult Failure to Thrive'' is defined as undefined weight loss, decreasing anthromorphic measurements, and a Palliative Performance Scale < 40 percent. It is also associated with multiple primary conditions contributing to the physical and functional decline of the individual. Four syndromes known to be individually predictive of adverse outcomes in older adults are repeatedly cited as prevalent in patients with ''adult failure to thrive'' impaired physical functioning, malnutrition, depression, and cognitive impairment. Data analysis using FY 2012 claims data for those beneficiaries with a reported principal hospice diagnosis of ''adult failure to thrive,'' and reported secondary diagnoses, shows that pneumonia, cerebral vascular accident (stroke), atrial fibrillation, heart disease, Alzheimer's disease, congestive heart failure, and Parkinson's disease are among the most common secondary diagnoses reported.

By the nature of the clinical criteria of ''debility'' and ''adult failure to thrive'', these symptom syndromes are the result of *multiple* primary conditions that contribute to the terminal decline. If any or all of these multiple primary conditions have been or are being treated or managed by a health care provider, or if medications have been prescribed for the patient to treat or manage any or all of these multiple primary conditions, we believe that these conditions meet the criteria of being established and/or confirmed by the beneficiary's health care provider and, thus, ''debility'' or ''adult failure to thrive'' would not be listed as the principal hospice diagnosis per ICD–9–CM coding guidelines.

Moreover, at the initial hospice election period, an eligible Medicare beneficiary must be certified as terminally ill. This certification is based on the recommendation of the medical director in consultation with, or with input from, the beneficiary's attending physician (if any) and a comprehensive assessment of all body systems. Per our regulations at § 418.25, Admission to Hospice Care, ''in reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information:

- Diagnosis of the terminal condition of the patient.
- Other health conditions, whether related or unrelated to the terminal condition.
- Current clinical relevant information supporting all diagnoses.''

All physical, emotional, and spiritual issues are assessed and an individualized, specific hospice plan of care is established by the hospice interdisciplinary team. A reported principal hospice diagnosis in the non-specific ICD–9–CM category, ''Symptoms, Signs, and Ill-Defined Conditions'', such as ''debility'' or ''adult failure to thrive,'' does not encompass the comprehensive, holistic nature of the assessment and care to be provided under the Medicare hospice benefit. For the eligible Medicare beneficiary who has elected the Medicare hospice benefit, and has been certified as terminally ill per the eligibility criteria, the hospice benefit provides services for all care related to the terminal illness, related conditions, and, for the management of pain and symptoms that result from the terminal illness and related conditions. If a non-specific, ill-defined diagnosis is reported as the principal hospice diagnosis, a comprehensive, individualized patient-centered plan of care, as required, may be difficult to accurately develop and implement, and, as a result, the hospice beneficiary may not receive the full benefit of hospice services. According to the hospice Conditions of Participation at § 418.56, ''The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including the following:

1. Interventions to manage pain and symptoms.

2. A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs.

3. Measurable outcomes anticipated from implementing and coordinating the plan of care.

4. Drugs and treatment necessary to meet the needs of the patient.

5. Medical supplies and appliances to meet the needs of the patient.

6. The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record''(42 CFR 418.56(c)).

A comprehensive hospice plan of care starts with accurate and thorough assessment and identification of the conditions contributing to the terminal illness and decline. ''Debility'' and ''adult failure to thrive'' are not appropriate principal diagnoses in the terminally ill population as these diagnoses are incongruous to the comprehensive nature of the hospice assessment, the specific, individualized hospice plan of and care, and the hospice services provided. CMS is aware that diagnosing diseases is not always a perfect science but the expectation is that based on the comprehensive hospice assessment, the certifying physicians are using their best clinical judgment in determining the principal diagnosis and related conditions.

In this proposed rule, we would clarify that ''debility'' and ''adult failure to thrive'' would not be used as principal hospice diagnoses on the hospice claim form. When reported as a principal diagnosis, these would be considered questionable encounters for hospice care, and the claim would be returned to the provider for a more definitive principal diagnosis. ''Debility'' and ''adult failure to thrive'' could be listed on the hospice claim as other, additional, or coexisting diagnoses. We believe that the private sector requires that ICD–9–CM coding guidelines be followed; this includes not allowing ''debility'' and ''adult failure to thrive'' as principal diagnoses on private sector hospice claims. The principal diagnosis listed should be determined by the certifying hospice physician(s) as the diagnosis *most contributory* to the terminal condition. When there are two or more interrelated conditions (such as diseases in the same ICD–9–CM chapter or manifestations characteristically associated with a certain disease) potentially meeting the definition of principal diagnosis, either condition may be sequenced first, unless the circumstances of the admission, the therapy provided, the Tabular List, or the Alphabetic Index indicate otherwise. In the unusual instance when two or more diagnoses equally meet the criteria for principal diagnosis as determined by the circumstances of admission, diagnostic workup and/or therapy provided, and the Alphabetic Index, Tabular List, or other coding guidelines do not provide sequencing direction, any one of the diagnoses may be sequenced first. We expect hospice providers to code the most definitive, contributory terminal diagnosis in the principal diagnosis field with all other related conditions in the additional diagnoses fields for hospice claims reporting. As stated previously, these clarifications are not intended to preclude any clinical judgment in determining a beneficiary's eligibility for hospice services. Therefore, CMS does not expect that these coding clarifications will create any limitations or barriers to accessing Medicare hospice services by eligible Medicare beneficiaries as coding on claims occurs after the beneficiary has elected and accessed hospice services. In fact, adherence to the ICD–9–CM coding guidelines should promote access to appropriate and comprehensive hospice services. We solicit comments regarding these ICD–9–CM coding guideline clarifications.

3. Use of ''Mental, Behavioral and Neurodevelopmental Disorders'' ICD–9–CM Codes

Another concerning trend noted in the top twenty claims-reported principal hospice diagnoses is the use of codes that fall under the classification of ''Mental, Behavioral and Neurodevelopmental Disorders.'' There are several codes that fall under this classification that encompass multiple dementia diagnoses that are frequently reported principal hospice diagnoses on hospice claims, but are not appropriate principal diagnoses per ICD–9–CM Coding Guidelines. Some of these ICD–9–CM codes are considered manifestation codes. In accordance with the 2012 ICD–9–CM Coding Guidelines, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD–9–CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a ''use additional code'' note at the etiology code, and a ''code first'' note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes, etiology followed by manifestation.'' In most cases, these manifestation codes will have in the code title, ''in diseases classified elsewhere'' or ''in conditions classified elsewhere.'' Codes with this in the title are a component of the etiology/manifestation convention. The codes with ''in diseases classified elsewhere'' or ''in conditions classified elsewhere'' in the title indicates that it is a manifestation code. ''In diseases classified elsewhere'' or ''in conditions classified elsewhere'' codes are never permitted to be used as first listed or principal diagnosis codes and they must be listed following the underlying condition.

However, there are manifestation codes that do not have ''in diseases classified elsewhere'' or ''in conditions classified elsewhere'' in their title. For such codes a ''use additional code'' note would still be present, and the rules for coding sequencing still apply. We note that several dementia codes which are not allowable as principal diagnoses per ICD–9–CM coding guidelines are under the classification of ''Mental, Behavioral and Neurodevelopmental Disorders.'' According to the ICD–9–CM coding guidelines for ''Mental, Behavioral and Neurodevelopmental Disorders'', dementias that fall under this category are ''most commonly a secondary manifestation of an underlying causal condition.'' Data analysis using FY 2012 claims data for those beneficiaries with a reported principal hospice diagnosis of a dementia classified under ''Mental, Behavioral and Neurodevelopmental Disorders'' and reported secondary diagnoses shows that Alzheimer's disease, Parkinson's disease, and stroke were the among the most common secondary diagnoses reported. Therefore, we are further reiterating the importance of following the ICD–9–CM coding guidelines for diagnosis reporting on the hospice claims submission.

There are, however, other ICD–9–CM dementia codes, such as those for Alzheimer's disease and others that fall under the ICD–9–CM classification, ''Diseases of the Nervous System and Sense Organs'' which are acceptable as principal diagnoses per ICD–9–CM coding guidelines. However, there are also dementia codes under this classification that do have manifestation/etiology or sequencing conventions; therefore, it is imperative that hospice providers follow ICD–9–CM coding guidelines and sequencing rules for all diagnoses and pay particular attention to dementia coding as there are dementia codes found in more than one ICD–9–CM classification chapter and there are multiple coding guidelines associated with these dementia conditions.

Again, these clarifications are not intended to preclude any clinical judgment in determining a beneficiary's eligibility for hospice services; rather these are clarifications regarding the reporting of dementia diagnoses on the hospice claims. We are restating that CMS expects hospice providers to code the most definitive, contributory terminal illness in the principal diagnosis field with all other related conditions in the additional diagnoses fields for hospice claims reporting. The reporting of accurate diagnoses of the principal terminal condition and all related conditions is keeping with the intent of the comprehensive, holistic nature of the Medicare hospice benefit. By adhering to these comprehensive assessment and diagnostic principals and coding guidelines, CMS expects that there will be no limitations or barriers to access to hospice care by eligible Medicare beneficiaries, and should; in fact, promote appropriate and comprehensive hospice services as per the original intent of the Medicare hospice benefit as proposed and finalized in the 1983 rules. We solicit comments regarding these ICD–9–CM coding guideline clarifications.

4. Guidance on Coding of Principal and Other, Additional, and/or Co-Existing Diagnoses

a. General Rules for Principal Diagnosis

Based on the ICD–9–CM coding guidelines, the circumstances of an inpatient admission always govern the selection of principal diagnosis. The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as ''that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.'' In analyzing frequently reported principal hospice diagnoses, data analysis revealed differences between reported principal hospice diagnoses and reported principal hospital diagnoses in patients who elected hospice within 3 days of discharge from the hospital. In analyzing data on cancer diagnoses of Medicare hospice beneficiaries for 2009 through 2011, Table 3 below shows that beneficiaries with a hospital-reported principal cancer diagnosis that elected hospice within three days of hospital discharge did not always have a hospice-reported principal cancer diagnosis. Although ICD–9–CM Coding Guidelines specify that the circumstances of an inpatient hospital admission diagnosis are to be used in determining the selection of a principal diagnosis, this guideline is not always being adhered to for the selection of the principal hospice diagnosis following a hospice beneficiary's inpatient hospitalization. It is unclear as to why there is this discrepancy in the hospital/hospice diagnosis patterns as ICD–9–CM Coding Guidelines are specific regarding principal diagnosis selection.

TABLE 3—PRINCIPAL HOSPICE DIAGNOSES AND INCIDENCE OF SAME DIAGNOSES FROM HOSPITALIZATIONS WITHIN THREE DAYS PRIOR TO HOSPICE ELECTION, FY 2009–2011

ICD–9 Diagnoses		Instances of principal hospital diagnosis . . .	. . . That then also became hospice principal diagnosis	
Label	ICD–9 Code ranges	Number	Number	Percent of total instances of principal hospital diagnosis
Lung & Chest Cavity Cancer	162–165s	32,428	27,939	86.2
Colo-Rectal Cancer	153–154s	10,360	8,270	79.8
Blood & Lymphatic Cancer	200–208s	15,491	12,747	82.3
Breast Cancer	174–175s	1,881	1,651	87.8
Pancreatic Cancer	157s	11,334	9,887	87.2
Prostate Cancer	185s	1,764	1,520	86.2
Liver Cancer	155–156s	6,710	5,009	74.6
Bladder Cancer	188s	2,844	2,218	78.0

Source: FY 2009–2011 Hospice claims matched with hospital inpatient claims where no more than three days passed between hospital discharge and hospice admission.

Note(s): Data sources included the Hospice Claims File (FYs 2009–2011) and the Hospitalizations File (FY 2009 through 2011). These two files were combined and records utilized for analysis were trimmed where Hospital Beneficiary ID equaled Hospice Beneficiary ID and Hospice Admit Date was within three days of Hospital Discharge Date. The data included the beneficiaries' ID number, their hospice admission date, the ICD–9 code for their principal hospice diagnosis, the hospital discharge date, and the ICD–9 code for their admitting hospital diagnosis.

Further, ICD–9–CM coding guidelines state, to list first the diagnosis shown in the medical record to be chiefly responsible for the services provided and to list additional codes that describe any coexisting conditions.

b. General Rules for Other (Additional) Diagnoses

For reporting purposes the definition for ''other diagnoses'' is interpreted as *additional* conditions that affect patient care in terms of requiring:

- clinical evaluation; or
- therapeutic treatment; or
- diagnostic procedures; or
- extended length of hospital stay; or
- increased nursing care and/or monitoring.

The UHDDS item #11–b defines Other Diagnoses as ''all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay''. Section IV.K of the ICD–9–CM Coding Guidelines addresses outpatient settings, and instructs providers to ''code all documented conditions at the time of the encounter/visit, and require or affect patient care treatment or management.'' These guidelines for determining principal and other diagnoses are stated in the ICD–9–CM Coding Guidelines.

We do not believe that requiring the reporting of other, additional, and/or coexisting diagnoses that are related to the terminal illness and related conditions would create a clinical or administrative burden on hospices. We note that some hospice providers are already reporting these diagnoses on their claims. Information on a patient's related and unrelated diagnoses should already be included as part of the hospice comprehensive assessment and appropriate interventions for the palliation and management of the terminal illness and related conditions should be incorporated into the patient's plan of care, as determined by the hospice interdisciplinary group

(IDG). The hospice Conditions of Participation (CoPs) at § 418.54(c)(2) require that the comprehensive assessment ''include complications and risk factors that affect care planning.'' The CoPs at § 418.56(e)(4) require that the hospice IDG ''provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.'' It is common for hospices to include the related and unrelated diagnoses on the comprehensive assessment in order to assure coordinated, holistic, patient care and to monitor the effectiveness of the care that is delivered.

With the specificity of both the ICD–9–CM coding guidelines and the ICD–10–CM coding guidelines, it is expected that complete, comprehensive coding will be applied to hospice claims submissions. Hospice providers are expected to report all coexisting or additional diagnoses related to the terminal illness and related conditions on the hospice claim to be in compliance with existing policy, and provide the data needed for evaluating potential hospice payment reform methodologies. This accurate coding of the principal hospice diagnosis and the other, additional, and/or coexisting diagnoses is in keeping with the comprehensive assessment and incorporated into the individualized hospice plan of care to aid hospices in identifying and meeting the hospice beneficiaries' needs. Currently, the hospice claim includes a field for the patient's principal hospice diagnosis, but allows for up to 17 additional diagnoses on the paper UB–04 claim, and up to 24 additional diagnoses on the 837I 5010 electronic claim.

5. Transition to ICD–10–CM

We note that ICD–10–CM will replace the ICD–9–CM on October 1, 2014. We would apply the coding clarifications discussed above to the ICD–10–CM coding guidelines, as well as the ICD–9–CM guidelines. A critical issue associated with the transition to ICD–10–CM involves the matter of crosswalking between the ICD–9–CM and ICD–10–CM code sets. The term ''crosswalking'' is generally defined as the act of mapping or translating a code in one code set to a code or codes in another code set. (The terms ''crosswalking'' and ''mapping'' are sometimes used interchangeably.) Understanding crosswalking will be important to physicians during the transition phase when learning which new ICD–10 code to use in place of an ICD–9 code. The National Center for Health Statistics (NCHS) has developed what is known as a ''General Equivalence Mappings'' (GEMs) for the diagnosis codes. Likewise, we have developed the GEMs for the procedure codes. The GEMs are considered to be the authoritative source for crosswalking between ICD–10 and ICD–9. The GEMs are data files that list the ICD–9 and ICD–10 codes and the attributes of the mapping between the two code sets. There is a file for mapping from ICD–10 to ICD–9 and another for mapping from ICD–9 to ICD–10. The GEMs files are available for free and can be downloaded from the NCHS Web site, *www.cdc.gov/nchs/icd/icd10cm.htm.* Hospices should not substitute crosswalking for learning and fully implementing ICD–10–CM into their procedures. Additional information regarding the transition to ICD–10–CM is available through the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10* and ICD–10–CM coding guidelines can be found on the CDC's Web site at *www.cdc.gov/nchs/data/icd10/10cmguidelines2012.pdf.*

B. Proposed Update to the Hospice Quality Reporting Program

1. Background and Statutory Authority

Section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0.0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular FY involved. Any such reduction would not be cumulative or be taken into account in computing the payment amount for subsequent FYs.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the consensus-based entity which holds a contract regarding performance measurement with the Secretary under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). However, section 1814(i)(5)(D)(ii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the Secretary may specify measures that are not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary. Section 1814(i)(5)(D)(iii) of the Act requires that the Secretary publish selected measures applicable with respect to FY 2014 no later than October 1, 2012.

2. Quality Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Year FY 2014

The successful development of a Hospice Quality Reporting Program (HQRP) that promotes the delivery of high quality healthcare services is our paramount concern. We seek to adopt measures for the HQRP that promote efficient and safer care. Our measure selection activities for the HQRP takes into consideration input we receive from the Measure Applications Partnership (MAP), convened by the National Quality Forum (NQF), as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide that input to CMS. Input from the MAP is located at: (*http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*). For more details about the pre-rulemaking process, see the FY 2013 IPPS/LTCH PPS final rule (77 FR at 53376 (August 31, 2012)).

We also take into account national priorities, such as those established by the National Priorities Partnership at (*http://www.qualityforum.org/npp/*), the HHS Strategic Plan *http://www.hhs.gov/secretary/about/priorities/priorities.html*), and the National Strategy for Quality Improvement in Healthcare located at (*http://www.healthcare.gov/news/reports/nationalqualitystrategy032011.pdf*). To the extent practicable, we have sought to adopt measures that have been

endorsed by the national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

As stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47302, 47320), to meet the quality reporting requirements for hospices for the FY 2014 payment determination as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

- An NQF-endorsed measure that is related to pain management, NQF #0209. The data collection period for this measure was October 1, 2012 through December 31, 2012, and the data submission deadline was April 1, 2013. The data for this measure are collected at the patient level, but are reported in the aggregate for all patients cared for within the reporting period, regardless of payer.
- A structural measure that is not endorsed by NQF: Participation in a Quality Assessment and Performance Improvement (QAPI) program that includes at least three quality indicators related to patient care. The data collection period for this measure was October 1, 2012 through December 31, 2012, and the data submission deadline was January 31, 2013. Hospices are not asked to report their level of performance on these patient care related indicators.

Hospices failing to report quality data before the specified deadline in 2013, would have their market basket update reduced by 2 percentage points in FY 2014. Hospice programs would be evaluated for purposes of the quality reporting program based on whether or not they submit data, not based on their performance level on required measures.

For the FY 2014 payment determination, hospices were asked to provide identifying information, and then complete a web based data entry for the required measures. For hospices that could not complete the web based data entry, a downloadable data entry form was made available upon request. Electronic data submission would be required for the FY 2015 payment determination and beyond; there would be no other data submission method available.

3. Quality Measures for Hospice Quality Reporting Program and Data Submission Requirements for Payment Year FY 2015 and Beyond

In the November 8, 2012 CY 2013 Home Health Prospective Payment System Rate Update final rule (77 FR 67068, 67133), to meet the quality reporting requirements for hospices for the FY 2015 payment determination and each subsequent year, as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

- The NQF-endorsed measure that is related to pain management, NQF #0209
- The structural measure: Participation in a Quality Assessment and Performance Improvement (QAPI) Program that includes at least three quality indicators related to patient care. We did not extend the requirement that hospices complete a check list of their patient care indicators and indicate the data sources they used for their quality indicators.

In this rule, we propose that the structural measure related to QAPI indicators and the NQF #0209 pain measure would not be required for the hospice quality reporting program beyond data submission for the FY 2015 payment determination. The original intent of the structural measure was for hospices to submit information about number, type, and data source of quality indicators used as a part of their QAPI Program. Data gathered as part of the structural measure were used to ascertain the breadth and context of existing hospice QAPI programs to inform future measure development activities including the data collection approach for the first year of required reporting (FY 2014). To date, hospices have reported two cycles worth of structural measure data to CMS:

- Voluntary reporting period (submitted to CMS by January 31, 2012)—For the voluntary reporting period hospices submitted free text data describing each quality indicator in their QAPI programs; data regarding number and data source of quality indicators were also submitted.
- FY 2014 (submitted to CMS by January 31, 2013)—For the FY 2014 cycle, hospices submitted data about the topic areas of care addressed by quality indicators in their QAPI Programs, using a drop-down menu checklist rather than free text to reduce burden. Data regarding number and data source of quality indicators were also submitted.

CMS has analyzed data from both reporting periods. Findings from the voluntary reporting period showed that hospices use quality indicators that address a wide range of patient care related topics and that there is great variation in how hospices collect and use ''standardized'' quality indicators. The majority of reported indicators addressed patient safety and physical symptom management. Likewise, findings from analysis of the FY 2014 structural measure data reiterated findings from the voluntary reporting period.

Other topics addressed included management of psychosocial aspects of care, bereavement and grief, communication, and care coordination. Overall, findings from both data collections of the structural measure have provided adequate information on hospice's patient care-related indicators making further reporting on the structural measure unnecessary.

In addition, we have determined that the NQF #0209 measure as it is currently collected and reported by hospices is not suitable for long term use as part of the Hospice Quality Reporting Program (HQRP). In making this decision, we considered findings from the Voluntary Reporting Period and the Hospice Item Set pilot. We will also examine data from the first year of reporting on the measure (impacting FY 2014 APU determination). In addition, we considered stakeholder input including comments submitted during rulemaking, expert input from a Technical Expert Panel (TEP), and provider questions and comments submitted to the hospice quality help desk during the 2012/2013 data collection and reporting period. There are two central concerns with the NQF #0209 measure. First, the measure does not easily correspond with the clinical processes for pain management, resulting in variance in what hospices collect, aggregate, and report. This concern could potentially be addressed by extensive and ongoing provider training or standardizing data collection. However, even with extensive training and the use of a standardized item set during the pilot test, the data showed continued variance in implementation of the measure. Second, there is a high rate of patient exclusion due to patient ineligibility for the measure and patients' denying pain at the initial assessment. This high rate of patient exclusion from the measure results in a small denominator and creates validity concerns. These concerns cannot be addressed by training or standardizing data collection. We recognize the value of measuring hospices' ability to achieve patient comfort and the desire to include a patient outcome measure such as the NQF #0209 in the HQRP. By removing the requirement that hospices submit the NQF #0209 measure, pain comfort would not be measured as part of the HQRP. However, we plan to collect two other measures that reflect care for pain. The standardized item set that CMS has developed contains data

elements to collect 7 quality measures endorsed by NQF for hospice. Among these are two process measures related to pain: The NQF #1634, Pain screening, and NQF #1637, pain assessment. However, while these measures provide insight about screening and assessment of patients, they do not offer information about patient comfort related to pain. An alternative proposal would be to retain NQF #0209 until a more suitable outcome measure was available for use in the HQRP, in order to maintain a focus on achieving patient comfort. We also recognize the importance of adherence to standardized data collection specifications when producing measures for public reporting. We intend to work toward the HQRP's future inclusion of an improved pain outcome measure. We solicit comment on the removal of the checklist and data source questions from the structural measure, and the removal of the NQF #0209 measure. We also solicit comment on the alternative proposal of maintaining NQF #0209 until another pain outcome measure is available.

4. Quality Measures for Hospice Quality Reporting Program for Payment Year FY 2016 and Beyond

As stated in the November 8, 2012 CY 2013 Home Health Prospective Payment System Rate Update final rule (77 FR 67068, 67133), we considered an expansion of the required measures to include additional measures endorsed by NQF. We also stated that to support the standardized collection and calculation of quality measures, collection of the needed data elements would require a standardized data collection instrument. We have developed and tested a hospice patient-level item set to be used by all hospices to collect and submit standardized data items about each patient admitted to hospice. We contracted with RTI International to support the development of the Hospice Item Set (HIS) for use as part of the HQRP. In developing the HIS, RTI focused on the NQF endorsed measures that had evidence of use and/or testing with hospice providers. Most of these measures were initially developed during the PEACE (Prepare, Embrace, Attend, Communicate, and Empower) Project, which was funded by CMS to develop and test an initial set of quality measures for use in hospice and palliative care. The PEACE project, which ended in 2008, resulted in the identification of recommended quality measure and data collection tools that hospice providers could use in their Quality Assessment and Performance Improvement (QAPI) programs to assess quality of care and target areas for improvement. Additional information on the PEACE project can be found at *http://www.thecarolinascenter.org/default.aspx?pageid=24*.

Most of the measures endorsed by NQF are already widely in use by hospices nationwide as part of their internal Quality Reporting and Performance Improvement (QAPI) programs. Data we received from hospices during the Voluntary Reporting Period in 2011 showed that hospices had implemented and were using the PEACE measures. Some of the PEACE measures were endorsed by NQF in February, 2012, and are listed below with their NQF endorsement numbers. The HIS standardizes the collection of the data elements that are needed to calculate seven of the NQF endorsed measures. The HIS was pilot tested during the early summer of 2012. The primary objective of the pilot was to explore data collection methods and the feasibility of implementing a patient-level item set for possible future use as part of the HQRP.

In developing the standardized HIS, we considered comments offered in response to the July 13, 2012 CY 2013 Home Health Prospective Payment System Rate Update proposed rule (77 FR 41548, 41573). We have included data items that support the following NQF endorsed measures for hospice:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen
- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1638 Dyspnea Treatment
- NQF #1639 Dyspnea Screening
- NQF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values Addressed (if desired by the patient)

To achieve a comprehensive set of hospice quality measures available for widespread use for quality improvement and informed decision making, and to carry out our commitment to develop a quality reporting program for hospices that uses standardized methods to collect data needed to calculate quality measures, we propose the implementation of the HIS in July 2014. We believe that to support the standardized collection and calculation of any or all of the hospice quality measures listed above, it is necessary to use a standardized data collection mechanism. The HIS was developed specifically for this data collection purpose. We expect the HIS Paperwork Reduction Act (PRA) package to post on or within several days after the publication of this FY 2014 Hospice proposed rule. The HIS will be posted on the Paperwork Reduction Act (PRA) area of the CMS.gov Web site at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/index.html*.

We propose that hospices begin the use and submission of the HIS in July 2014. To meet the quality reporting requirements for hospices for the FY 2016 payment determination and each subsequent year, we propose regular and ongoing electronic submission of the HIS data for each patient admitted to hospice on or after July 1, 2014, regardless of payer. Hospices would be required to complete and submit an admission HIS and a discharge HIS for each patient. Hospices failing to report quality data via the HIS in 2014 would have their market basket update reduced by 2 percentage points in FY 2016. Hospice programs would be evaluated for purposes of the quality reporting program based on whether or not they submit data, instead of their performance level on required measures. If our proposals for use of the Hospice Item Set are finalized, we plan to provide Hospices with further information and details about use of the Hospice Item Set. We will provide this information through venues such as postings on the Hospice Quality Reporting Program Web page, Special Open Door Forums, announcements in the CMS E-News, providers training, and National Provider calls. Electronic data submission would be required for HIS submission in CY 2014 and beyond; there would be no other data submission method available. We would make available submission software for the HIS to hospices at no cost. We would also provide reports to individual hospices on their performance on the measures calculated from data submitted via the HIS. The specifics of the reporting system and precisely when specific measures would be made available have not yet been determined. We would report to providers on the following measures on a schedule to be determined:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen
- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1638 Dyspnea Treatment
- NQF #1639 Dyspnea Screening
- NQF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values Addressed (if desired by the patient)

TABLE 4—SUMMARY TABLES

Data collection	Data submission	APU Impact	Measure name
Finalized in the CY 2013 HH PPS Final Rule			
1/1/2013–12/31/2013	4/1/2014	FY 2015 (10/1/2014)	Structural/QAPI measure, NQF #0209.
Proposed in this Proposed Rule			
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Hospice and Palliative Care—Pain Screening, NQF #1634.
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Hospice and Palliative Care—Pain Assessment, NQF #1637.
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Hospice and Palliative Care—Dyspnea Screening, NQF #1639.
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Hospice and Palliative Care—Dyspnea Treatment, NQF #1638.
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Patients Treated with an Opioid who are Given a Bowel Regimen, NQF #1617.
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Hospice and Palliative Care—Treatment Preferences, NQF #1641.
7/1/2014–12/31/2014	Rolling	FY 2016 (10/1/2015)	Beliefs/Values Addressed (if desired by patient), NQF #1647.

As stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47302, 47320), we finalized that all hospice quality reporting periods subsequent to that for Payment Year FY 2014 would be based on a CY instead of a calendar quarter and for FY 2015 and beyond, the data submission deadline would be April 1st of each year. Our proposal to implement the HIS in July 2014 would negate the CY data collection requirement and the April 1st data submission deadline. We would provide details on data collection and submission timing prior to implementation of the HIS in July 2014.

5. Public Availability of Data Submitted

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. The procedures ensure that a hospice would have the opportunity to review the data regarding the hospice's respective program before it is made public. In addition, under section 1814(i)(5)(E) of the Act, the Secretary is authorized to report quality measures that relate to services furnished by a hospice on the CMS Web site. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for public reporting of hospice quality data. We also recognize it is essential that the data made available to the public be meaningful and that comparing performance between hospices requires that measures be constructed from data collected in a standardized and uniform manner. The development and implementation of a standardized data set for hospices must precede public reporting of hospice quality measures. Once hospices have implemented the standardized data collection approach, we will have the data needed to establish the scientific soundness of the quality measures that can be calculated using the standardized data collection. It is critical to establish the reliability and validity of the measures prior to public reporting in order to demonstrate the ability of the measures to distinguish between the quality of services provided. To establish reliability and validity of the quality measures, at least four quarters of data will need to be analyzed. Typically the first two quarters of data reflect the learning curve of the providers as they adopt a standardized data collection; these data are not used to establish reliability and validity. This means that if the proposal to begin data collection in CY 2014 (Q3) is finalized, the data from CY 2014 (Q3, Q4) would not be used for assessing validity and reliability of the quality measures. Data collected by hospices during CY 2015 would be analyzed starting in CY 2015. Decisions about whether to report some or all of the quality measures publicly would be based on the findings of analysis of the CY 2015 data. In addition, as noted, the Affordable Care Act requires that reporting be made public on a CMS Web site and that providers have an opportunity to review their data prior to public reporting. CMS will develop the infrastructure for public reporting, and provide hospices an opportunity to review their data. In light of all the steps required prior to data being publicly reported, we anticipate that public reporting will not be implemented in FY 2016. Public reporting may occur during the FY 2018 APU year, allowing ample time for data analysis, review of measures' appropriateness for use for public reporting, and allowing hospices the required time to review their own data prior to public reporting. We will announce the timeline for public reporting of data in future rulemaking. We welcome public comment on what we should consider when developing future proposals related to public reporting.

6. Proposed Adoption of the CMS Hospice Experience of Care Survey for the FY 2017 Payment Determination and That of Subsequent Fiscal Years

In the CY 2013 Home Health Prospective Payment System Rate Update final rule (77 FR 67135), we stated that were considering the use of a patient/family experience of care survey in addition to other hospice quality of care (clinical) measures. We are currently developing a Hospice Experience of Care Survey questionnaire drawing heavily on questionnaires in the public domain such as the Family Evaluation of Hospice Care (FEHC). The Hospice Experience of Care Survey would treat the dying patient and his or her informal caregivers (family members or friends) as the unit of care.

Before the development of this survey, there was no official national standard experience of care survey that included standard survey administration protocols. This is one reason we did not adopt the FEHC as

our experience of care survey. In addition, topic areas that were not addressed by the FEHC were identified by the public as important to their experiences. The Hospice Experience of Care Survey would include detailed survey administration protocols which would allow for comparisons across hospices. The survey would focus on topics that are important to hospice users and for which informal caregivers are the best source for gathering this information. In addition, the ''About You'' section of the instrument includes demographic characteristics of the patients and their caregivers which can be used to feed into case mix adjustments of the publicly reported data.

The Hospice Experience of Care Survey now under development would seek information from informal caregivers of patients who died while enrolled in hospices. We plan to field the questionnaires after the patient's death. Fielding timelines would be established to give the respondent some time from the death of their loved one, while simultaneously not delaying so long that the respondent is likely to forget details of the hospice experience. Caregivers would be presented with a set of standardized questions about their own experiences and the experiences of the patient in hospice care. During national implementation of this survey, hospices would be required to offer the survey, but individual caregivers would respond only if they voluntarily chose to do so.

The Hospice Experience of Care Survey captures such topics as hospice provider communications with patients and family members, hospice provider care, and patient and family member characteristics. The survey would allow the informal caregiver (family member or friend) to provide an overall rating of the hospice care their patient received, and would ask if they would recommend ''this hospice'' to others.

The Hospice Experience of Care Survey is undergoing development in accordance with the principles used in the development of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys. Therefore, we are—

- Obtaining input from consumers and stakeholders regarding how hospice patients perceive hospice care and what elements in hospice programs are of greatest importance to patients and informal caregivers.
- Drafting a version of the hospice questionnaire that would be cognitively tested with a small number of respondents in both English and Spanish. This type of testing will allow us to assess how respondents interpret and respond to individual questionnaire items.
- Providing a pilot test of the Hospice Experience of Care Survey instrument after the development of an initial questionnaire is completed. This pilot test would allow us to review survey implementation procedures and use statistical analysis of the survey results to select the final set of questions. In addition, it will allow us to select variables which may be used in the case mix adjustment of survey results for public reporting.

The Hospice Experience of Care Survey, as well as the CAHPS® family of surveys, focuses on patient perspectives on the experience of care, rather than on patient satisfaction. CAHPS® data complements other data, including clinical measures. CAHPS® surveys are specifically intended to focus on issues where the patient (or in this case the caregiver) is the best source of information. We intend the Hospice Experience of Care Survey to have a similar focus.

We are planning to move forward with a model of survey administration in which we would approve and train survey vendors to administer the survey on behalf of hospices. Hospices would be required to contract with an approved survey vendor and to provide the sampling frame to the approved vendor on a monthly basis. The following are proposed key dates for the national implementation of the Hospice Experience of Care Survey:

- Based on the model of CMS-implemented CAHPS® surveys (that is, Hospital CAHPS® and Home Health Care CAHPS®), we propose that hospices would contract with a CMS-approved survey vendor to conduct a ''dry run'' of the survey for at least 1 month in the first quarter of CY 2015 (January 2015 through March 2015). Vendors would submit data on the hospice's behalf to the CMS hospice patient experience data center. The deadline for data submission has not yet been finalized. For the ''dry run'' the survey vendor would follow all the national implementation procedures, but the data would not be publicly reported. The dry run would provide hospices and their vendors with the opportunity to work together under ''test'' conditions before they are required to start publicly reporting data.

We propose that hospices would contract with CMS-approved vendors to begin continuous monthly data collection starting April 1, 2015. Data submission dates are being developed; however, we expect that data would be submitted quarterly.

- We propose that the FY 2017 Annual Payment Update (APU) determination, based in part on the Hospice Experience of Care Survey, would include a dry run for at least 1 month in the first quarter of CY 2015 (January 2015, February 2015, and/or March 2015) plus 3 quarters of continuous monthly participation (April 1, 2015 through December 31, 2015).
- We propose that subsequent APU determinations would be based upon 4 quarters of continuous monthly participation from January 1 through December 31 of the relevant CY.
- We propose to exempt very small hospices from the survey requirements. Hospices that had fewer than 50 unduplicated or unique deceased patients in the period from January 1, 2014 through December 31, 2014 would be exempt from the Hospice Experience of Care Survey data collection and reporting requirements for the FY 2017 payment determination. The hospices would be required to submit their patient counts for the period of January 1, 2014 through December 31, 2014 to CMS. Data submission procedures would be further specified in future rules. There would be similar exemptions for subsequent APU determinations. However, a hospice would need to submit to CMS their patient count for each future period to qualify for this exemption.

As part of the national implementation, we would develop technical specifications for vendors to follow and would issue a detailed survey guidelines manual prior to the dry run months.

In addition, there would be a Web site devoted specifically to the Hospice Survey. It would include information and updates regarding survey implementation and technical assistance. Hospices interested in viewing similar model Web sites are encouraged to visit the Hospital CAHPS® Web site at *www.hcahpsonline.org* or to the Home Health Care CAHPS® Web site at *https://homehealthcahps.org.* On these Web sites, viewers can see and download the detailed manuals about the surveys (the *Quality Assurance Guidelines* for Hospital CAHPS® and the *Protocols and Guidelines Manual* for Home Health Care CAHPS®), as well as obtain information about the surveys' histories, data submission information, and survey updates.

Consistent with our other implemented surveys, we would provide an email address and toll-free telephone number for technical assistance.

The Affordable Care Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to the FY. Any such reduction would not be cumulative and would not be taken into account in computing the payment amount for subsequent FYs. In the November 8, 2012 CY 2013 Home Health Prospective Payment System final rule (77 FR 67068), it was stated that all hospice quality reporting periods subsequent to that for Payment Year 2014 be based on a CY rather than on a FY. With the proposed dry run timeline of least 1 month in the first quarter of CY 2015 and data collection beginning April 1, 2015, we propose that the survey requirements be part of the Hospice Quality Reporting Program requirements for the FY 2017 payment determination. We are proposing that to meet the FY 2017 requirements, hospices would participate in a dry run for at least 1 month of the first quarter of CY 2015 (January 2015, February 2015, and/or March 2015) and must collect the survey data on a monthly basis from April 1, 2015 through December 31, 2015.

In summary, we are proposing to start the Hospice Experience of Care Survey requirements with a test run for at least 1 month in the first quarter of CY 2015 with continuous monthly data collection beginning April 1, 2015, to meet the annual payment update requirements for FY 2017. We are proposing to add the Hospice Experience of Care Survey requirements to the Hospice quality reporting program requirements for the FY 2017 annual payment update. Participating hospices would have to contract with an approved Hospice Experience of Care Survey vendor to conduct the survey on their behalf.

7. Notice Pertaining to Reconsiderations Following APU Determinations

At the conclusion of any given quality data reporting period, we would review the data received from each hospice during that reporting period to determine if the hospice has met the reporting requirements. Hospices that are found to be non-compliant with the reporting requirements set forth for that reporting cycle could receive a reduction in the amount of 2 percentage points to their annual payment update for the upcoming payment year.

We are aware that there may be situations when a hospice has evidence to dispute a finding of non-compliance. We further understand that there may be times when a provider may be prevented from submitting quality data due to the occurrence of extraordinary circumstances beyond their control (for example, natural disasters). It is our goal not to penalize hospice providers in these circumstances or to unduly increase their burden during these times.

Other CMS Quality Reporting Programs, such as Home Health Quality Reporting and Inpatient Quality Reporting, include an opportunity for providers to request a reconsideration pertaining to their APU determinations. We are aware of the potential need for providers to request reconsideration and that we will be making APU determinations for FY 2014 in the coming months. Therefore, to be consistent with other established quality reporting programs, we are using this proposed rule to notify providers of our intent to provide a process that would allow hospices to request reconsiderations pertaining to their FY 2014 and subsequent years' payment determinations.

Specifically, as part of the reconsideration process for hospices beginning with the FY 2014 payment determinations, hospices found to be non-compliant with the reporting requirements during a given reporting cycle would be notified of that finding. The purpose of this notification is to put hospices on notice of the following: (1) That they have been identified as being non-compliant with section 3004 of the Affordable Care Act for the reporting cycle in question; (2) that they would be scheduled to receive a reduction in the amount of 2 percentage points to the annual payment update to the applicable fiscal year; (3) that they may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or that if they were non-compliant, they have a valid and justifiable excuse for this non-compliance; and, (4) that they must follow a defined process on how to file a request for reconsideration, which would be described in the notification.

Upon the conclusion of our review of each request for reconsideration, we would render a decision. We could reverse our initial finding of non-compliance if: (1) The hospice provides proof of full compliance with the all requirements during the reporting period; or (2) the hospice was not able to comply with requirements during the reporting period, and it provides adequate proof of a valid or justifiable excuse for this non-compliance. We would uphold our initial finding of non-compliance if the hospice could not show any justification for non-compliance.

We would provide details of the reconsideration process, including mechanisms of notification, time frames and mechanisms for filing requests for reconsideration, required content for requests, required supporting documentation, and mechanisms of notification of final determinations on the HQRP section of cms.gov and by program instruction this spring.

C. FY 2014 Rate Update

1. Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments and our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions. We have consistently used the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index. In our August 4, 2005 FY 2006 Hospice Wage Index final rule (70 FR 45130), we began adopting the revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of Core-Based Statistical Areas (CBSAs). The bulletin is available online at *http://www.whitehouse.gov/omb/bulletins/b03-04.html*. In the FY 2006 Hospice Wage Index final rule, we implemented a 1-year transition policy using a 50/50 blend of the CBSA-based wage index values and the MSA-based wage index values for FY 2006. The one-year transition policy ended on September 30, 2006. For FY 2007 and beyond, we have used CBSAs exclusively to calculate wage index values. OMB has published subsequent bulletins regarding CBSA changes. The most recent CBSA changes used for the FY 2014 hospice wage index are found in OMB Bulletin 10–02, available at: *http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf*.

When adopting OMB's new labor market designations in FY 2006, we identified some geographic areas where there were no hospitals, and thus, no hospital wage index data, which to base

the calculation of the hospice wage index. We also adopted the policy that for urban labor markets without a hospital from which hospital wage index data could be derived, all of the CBSAs within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas in our August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39386). In FY 2014, the only CBSA without a hospital from which hospital wage data could be derived is 25980, Hinesville-Fort Stewart, Georgia.

In our August 31, 2007 FY 2008 Hospice Wage Index final rule (72 FR 50214), we implemented a new methodology to update the hospice wage index for rural areas without a hospital, and thus no hospital wage data. In cases where there was a rural area without rural hospital wage data, we used the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs to represent a reasonable proxy for the rural area. In our August 31, 2007 FY 2008 Hospice Wage Index final rule, we noted that we interpret the term ''contiguous'' to mean sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, our policy of imputing a rural pre-floor, pre-reclassified hospital wage index based on the pre-floor, pre-reclassified hospital wage index (or indices) of CBSAs contiguous to a rural area without a hospital from which hospital wage data could be derived does not recognize the unique circumstances of Puerto Rico. While we have not identified an alternative methodology for imputing a pre-floor, pre-reclassified hospital wage index for rural Puerto Rico, we will continue to evaluate the feasibility of using existing hospital wage data and, possibly, wage data from other sources. For FY 2008 through FY 2013, we have used the most recent pre-floor, pre-reclassified hospital wage index available for Puerto Rico, which is 0.4047. In this proposed rule, for FY 2014, we continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

For FY 2014, we would use the 2013 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the hospice wage. We would continue to use the pre-floor, pre-reclassified hospital wage data as a basis to determine the hospice wage index values because hospitals and hospices both compete in the same labor markets, and therefore, experience similar wage-related costs. We believe the use of the pre-floor, pre-reclassified hospital wage index data, as a basis for the hospice wage index, results in the appropriate adjustment to the labor portion of the costs. The FY 2014 hospice wage index values presented in this proposed rule were computed consistent with our pre-floor, pre-reclassified hospital (IPPS) wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments for hospice). The FY 2013 pre-floor, pre-reclassified hospital wage index does not reflect OMB's new area delineations, based on the 2010 Census, as outlined in OMB Bulletin 13–01, released on February 28, 2013. Moreover, the proposed FY 2014 pre-floor, pre-reclassified hospital wage index does not contain OMB's new area delineations because those changes will be in the FY 2014 IPPS proposed rule, which will be published in the **Federal Register**, in the near future. CMS intends to propose changes to the FY 2015 hospital wage index based on the newest CBSA changes in the FY 2015 IPPS proposed rule. Therefore, if CMS incorporates OMB's new area delineations, based on the 2010 Census, in the FY 2015 hospital wage index, those changes would also be reflected in the FY 2016 hospice wage index.

2. FY 2014 Hospice Wage Index With an Additional 15 Percent Reduced Budget Neutrality Adjustment Factor (BNAF)

This proposed rule would update the hospice wage index values for FY 2014 using the FY 2013 pre-floor, pre-reclassified hospital wage index. As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are then subject to either a budget neutrality adjustment or application of the hospice floor to compute the hospice wage index used to determine payments to hospices. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by either: (1) The hospice budget neutrality adjustment factor (BNAF); or (2) the hospice floor subject to a maximum wage index value of 0.8; whichever results in the greater value.

The BNAF is calculated by computing estimated payments using the most recent, completed year of hospice claims data. The units (days or hours) from those claims are multiplied by the updated hospice payment rates to calculate estimated payments. For the FY 2014 Hospice Wage Index proposed rule, that means estimating payments for FY 2014 using units (days or hours) from FY 2012 hospice claims data, and applying the FY 2014 hospice payment rates. The FY 2014 hospice wage index values are then applied to the labor portion of the payments. The procedure is repeated using the same units from the claims data and the same payment rates, but using the 1983 Bureau of Labor Statistics (BLS)-based wage index instead of the updated raw pre-floor, pre-reclassified hospital wage index (note that both wage indices include their respective floor adjustments). The total payments are then compared, and the adjustment required to make total payments equal is computed; that adjustment factor is the BNAF.

The August 6, 2009 FY 2010 Hospice Wage Index final rule finalized a provision to phase out the BNAF over 7 years, with a 10 percent reduction in the BNAF in FY 2010, and an additional 15 percent reduction in each of the next 6 years, with complete phase out in FY 2016 (74 FR 39384). Once the BNAF is completely phased out, the hospice floor adjustment would simply consist of increasing any wage index value less than 0.8 by 15 percent, subject to a maximum wage index value of 0.8. Therefore, in accordance with the FY 2010 Hospice Wage final rule, the BNAF for FY 2014 will be reduced by an additional 15 percent for a total BNAF reduction of 70 percent (10 percent from FY 2010, an additional 15 percent from FY 2011, an additional 15 percent for FY 2012, an additional 15 percent for FY 2013 and an additional 15 percent in FY 2014).

The unreduced BNAF for FY 2014 is 0.061498 (or 6.1498 percent). A 70 percent reduction to the BNAF is computed to be 0.018449 (or 1.8449 percent). For FY 2014, this is mathematically equivalent to taking 30 percent of the unreduced BNAF value, or multiplying 0.061498 by 0.30, which equals 0.018449 (1.8449 percent). The BNAF of 1.8449 percent reflects a 70 percent reduction in the BNAF. The 70 percent reduced BNAF (1.8449 percent) was applied to the pre-floor, pre-reclassified hospital wage index values of 0.8 or greater.

The 10 percent reduced BNAF for FY 2010 was 0.055598, based on a full BNAF of 0.061775; the additional 15 percent reduced BNAF FY 2011 (for a cumulative reduction of 25 percent) was 0.045422, based on a full BNAF of 0.060562; the additional 15 percent reduced BNAF for FY 2012 (for a cumulative reduction of 40 percent) was 0.035156, based on a full BNAF of 0.058593; the additional 15 percent reduced BNAF for FY 2013 (for a cumulative reduction of 55 percent) was 0.027197, based on a full BNAF of

0.060438; and the additional 15 percent reduced BNAF for FY 2014 (for a cumulative reduction of 70 percent) is 0.018449, based on a full BNAF of 0.061498.

Hospital wage index values which are less than 0.8 are subject to the hospice floor calculation. For example, if in FY 2013, County A had a pre-floor, pre-reclassified hospital wage index (raw wage index) value of 0.3994, we would perform the following calculations using the budget-neutrality factor (which for this example is an unreduced BNAF of 0.061498, less 70 percent, or 0.018449) and the hospice floor to determine County A's hospice wage index:

Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1 + 70 percent reduced BNAF: (0.3994 × 1.018449 = 0.4068); Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1 + hospice floor: (0.3994 × 1.15 = 0.4593).Based on these calculations, County A's hospice wage index would be 0.4593. The BNAF may be updated for the final rule based on availability of more complete data.

An addendum A and Addendum B with the FY 2014 wage index values for rural and urban areas will not be published in the **Federal Register**. The FY 2014 wage index values for rural areas and urban areas are available via the internet at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html*. The hospice wage index for FY 2014 set forth in this proposed rule includes the BNAF reduction and would be effective October 1, 2013 through September 30, 2014.

3. Hospice Payment Update Percentage

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the market basket index, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the market basket percentage for that FY. The Act requires us to use the inpatient hospital market basket to determine the hospice payment rate update. In addition, section 3401(g) of the Affordable Care Act mandates that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, section 3401(g) of the Affordable Care Act also mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). The proposed hospice payment update percentage for FY 2014 is based on the inpatient hospital market basket update of 2.5 percent (based on IHS Global Insight, Inc.'s first quarter 2013 forecast with historical data through the fourth quarter of 2012). A detailed description of how the inpatient hospital market basket is derived will be available in the FY 2014 IPPS proposed rule, which will be published in the **Federal Register**, in the near future. Due to the requirements at 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2014 of 2.5 percent must be reduced by a productivity adjustment as mandated by Affordable Care Act (currently estimated to be 0.4 percentage point for FY 2014). The estimated inpatient hospital market basket for FY 2014 is reduced further by a 0.3 percentage point, as mandated by the Affordable Care Act. In effect, the proposed hospice payment update percentage for FY 2014 is 1.8 percent. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market basket and productivity adjustment), we would use such data, if appropriate, to determine the FY 2014 market basket update and the multi-factor productivity MFP adjustment in the FY 2014 Hospice PPS final rule.

Currently, the labor portion of the hospice payment rates is as follows: for Routine Home Care, 68.71 percent; for Continuous Home Care, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. Therefore, the non-labor portion of the payment rates is as follows: for Routine Home Care, 31.29 percent; for Continuous Home Care, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent.

4. Proposed Updated FY 2014 Hospice Payment Rates

Historically, the hospice rate update has been published through a separate administrative instruction issued annually in the summer to provide adequate time to implement system change requirements; however, starting in this FY 2014 rule and for subsequent fiscal years, we propose to use rulemaking as the means to propose hospice payment rates. This change is proposed to be consistent with the rate update process in other Medicare benefits, and should provide rate information to hospices as quickly as, or earlier than, when rates are published in an administrative instruction.

There are four payment categories that are distinguished by the location and intensity of the services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the routine home care rate for each day the beneficiary is enrolled in hospice, unless the hospice provides continuous home care, inpatient respite care, or general inpatient care. Continuous home care is provided during a period of patient crisis to maintain the patient at home, inpatient respite care is short-term care to allow the usual caregiver to rest, and general inpatient care is to treat symptoms that cannot be managed in another setting.

The proposed FY 2014 payment rates would be the FY 2013 payment rates, increased by 1.8 percent, which is the proposed hospice payment update percentage for FY 2014 as discussed in section III.C.3. The proposed FY 2014 hospice payment rates would be effective for care and services furnished on or after October 1, 2013, through September 30, 2014.

TABLE 5—PROPOSED FY 2014 HOSPICE PAYMENT RATES UPDATED BY THE PROPOSED HOSPICE PAYMENT UPDATE PERCENTAGE

Code	Description	FY 2013 payment rates	Multiply by the FY 2014 proposed hospice payment update of 1.8 percent	FY 2014 Proposed payment rate	Labor Share of the proposed payment rate	Non-Labor share of the proposed payment rate
651	Routine Home Care	$153.45	× 1.018	$156.21	$107.33	$48.88
652	Continuous Home Care Full Rate = 24 hours of care $=37.99 hourly rate	895.56	× 1.018	911.68	626.42	285.26
655	Inpatient Respite Care	158.72	× 1.018	161.58	87.46	74.12
656	General Inpatient Care	682.59	× 1.018	694.88	444.79	250.09

The Congress required in sections 1814(i)(5)(A) through (C) of the Act that hospices begin submitting quality data, based on measures to be specified by the Secretary. Beginning in FY 2014, hospices which fail to report quality data will have their market basket update reduced by 2 percentage points. In the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47320 through 47324), we implemented a hospice Quality Reporting Program (QRP) as required by section 3004 of the Affordable Care Act. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Hospices failing to report quality data in 2013 will have their market basket update reduced by 2 percentage points in FY 2014.

TABLE 6—PROPOSED FY 2014 HOSPICE PAYMENT RATES UPDATED BY THE PROPOSED HOSPICE PAYMENT UPDATE PERCENTAGE FOR HOSPICES THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2013 payment rates	Multiply by the FY 2014 proposed hospice payment update percentage of 1.8 percent percent minus 2 percentage points (−0.2)	FY 2014 Proposed payment rate
651	Routine Home care	$153.45	× 0.998	$153.14
652	Continuous Home Care Full Rate= 24 hours of care $=37.99 hourly rate.	895.56	× 0.998	893.77
655	Inpatient Respite Care	158.72	× 0.998	158.40
656	General Inpatient Care	682.59	× 0.998	681.22

A Change Request with the finalized hospice payment rates, a finalized hospice wage index, the Pricier for FY 2014, and the hospice cap amount for the cap year ending October 31, 2013 would continue to be issued in the summer.

D. Update on Hospice Payment Reform and Data Collection

In 2010, the Congress amended section 1814(i)(6) of the Act with section 3132(a) of the Affordable Care Act. The amendment authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and for other purposes. The types of data and information described in the Act would capture resource utilization and other measures of cost, which can be collected on claims, cost reports, and possibly other mechanisms as we determine to be appropriate. The data collected may be used to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we are required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

This section of the proposed rule contains three subsections which update the public or discuss different aspects of hospice payment reform; there are no proposals in any of these three subsections.

1. Update on Reform Options

Our hospice contractor, Abt Associates, continues to conduct research and analyses, to identify potential data collection needs, and to research and develop hospice payment model options. To date, we completed an environmental scan; a draft analytic plan; and convened technical advisory panel meetings under the initial contract with Abt in 2010. We are continuing with these efforts under a contract awarded in September 2011. In June 2012, we convened stakeholder meetings where research findings were presented on potential payment system vulnerabilities; utilization of the Medicare hospice benefit, including general inpatient care use during the period the beneficiary is enrolled in hospice care; analysis of hospice cost reports; and the effects of the face-to-face encounter requirement. These and other findings are described in the Abt Hospice Study Technical Report, which is available on the CMS Hospice Center Web page, at *http://www.cms.gov/Center/Provider-Type/Hospice-Center.html*.

Additionally, we continue to conduct analyses of various payment reform model options under consideration. These models include a U-shaped model of resource use which MedPAC recommended that we adopt, and which is described in Chapter 6 of its March,

2009 report entitled ''Report to the Congress: Medicare Payment Policy'' (available online at: *http://www.medpac.gov/chapters/Mar09_Ch06.pdf*). MedPAC determined that the level of Medicare payment to a hospice under the current per diem payment system is constant throughout a hospice patient's stay. The report noted that the constancy of the per diem payment over the course of a hospice stay is misaligned with a hospice's costs during the stay. A hospice's costs typically follow a U-shaped curve, with higher costs at the beginning and end of a stay, and lower costs in the middle of the stay. This cost curve reflects hospices' higher service intensity at the time of the patient's admission and the time surrounding the patient's death (MedPAC, page 358). Payment under a U-shaped model would be higher at the beginning and end of a hospice stay, and lower in the middle portion of the stay.

The analysis found that very short hospice stays have a flatter curve than the U-shaped curve seen for longer stays, and that average hospice costs are much higher. These short stays are less U-shaped because there is not a lower-cost middle period between the time of admission and the time of death. As such, we are also considering a tiered approach, with payment tiers based on the length of stay. For example, payment for stays of 5 days or less (which occurred for about 25 percent of hospice beneficiaries in 2011) could be made under a per diem system that accounts for the higher hospice costs, with no variation in the rate based on length of stay as would occur under a U-shaped model. Payment for longer stays, where costs follow more of a U-shape, could be made under a tier based on the U-shaped payment model, where the per diem amount fluctuates depending upon whether the days billed are at the beginning, middle, or end of the stay.

Another option is to analyze whether a short-stay add-on payment, similar to the home health Low Utilization Payment Amount (LUPA) add-on, would improve payment accuracy if we retain the current per diem system. The LUPA add-on is made for home health patients who require four or fewer visits during the 60-day episode. These home health episodes are paid based on the visits actually furnished during the episode. For LUPA episodes that occur as the only episode or the first episode in a sequence of adjacent home health episodes for a given beneficiary, an increased payment is made to account for the front-loading of costs (see *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HomeHlthProspaymt.pdf* for more information).

Finally, as we collect more accurate diagnosis data, including data on related conditions, we would also evaluate whether case-mix should play a role in determining payments.

a. Rebasing the Routine Home Care (RHC) Rate

We are updating our review of the hospice RHC rate, but are not including any proposals at this time. Rebasing the RHC rate involves using the existing components that make up the rate, and recalculating based on more current data. RHC is the basic level of care under the Hospice benefit, where a beneficiary receives hospice care, but remains at home. With this level of care, hospice providers are reimbursed per day regardless of the volume or intensity of services provided to a beneficiary on any given day. It is anticipated that there will be days when a beneficiary does not require any services, as well as days when a beneficiary requires several visits from the hospice provider.

When the hospice benefit was created in 1983, the RHC base payment rate was set using nine different components of cost from a relatively small set of hospices (n=26) that were participating in a CMS hospice demonstration, as described in the December 16, 1983 Hospice final rule (48 FR 56008). The nine cost components were: nursing care ($16.25); home health aide ($12.74); social services/therapy ($3.23); home respite ($1.46); interdisciplinary group ($2.78); drugs ($1.18); supplies ($4.49); equipment ($1.13); and outpatient hospital therapies ($2.99). The sum of all the components' costs equaled the base payment rate for RHC as stated in that 1983 hospice final rule. The original RHC rate was set at $46.25. In addition to RHC, we also established three other levels of care for hospice care from data obtained from the Medicare hospice demonstration project: Continuous Home Care (CHC), Inpatient Respite Care (IRC) and General Inpatient Care (GIP).

It is CMS' intent to ensure that reimbursement rates under the Hospice benefit align as closely as possible with the average costs hospices incur when efficiently providing covered services to beneficiaries. As we continue to gather and analyze more data for payment reform, we have found evidence of a potential misalignment between the current RHC payment rate and the cost of providing RHC. One potential option to address this misalignment could be to rebase the hospice RHC rate, though we are not proposing to do so at this time, so that the cost categories established in the rate reflect the changes in the utilization of hospice services provided for palliation and management of terminally ill patients. However, we are still evaluating data and are currently not proposing any changes to address the misalignment.

At this time, we do not have the data to support rebasing six of the nine cost components described in the 1983 final rule. Information on the utilization of drugs, supplies, and equipment is not available from hospice claims data, and the corresponding information that is available from cost reports, such as outpatient hospital therapies, is not sufficiently detailed to allow for rebasing. One approach to consider in more closely aligning RHC payments with costs is to rebase the three clinical service components (nursing, home health aide, social services/therapy) that currently comprise 69.7 percent of the RHC rate by calculating the average cost per day, weighted by the number of RHC days, for each of the three components using FY 2011 cost report data matched to FY 2011 claims data. As part of rebasing the RHC rate we would then inflate the 1983 cost per day for each of the six remaining components by a factor of 3.1704, which corresponds to the market basket increases between 1983 and 2011.[4] We note that our cost report analysis thus far found that drug costs over the years have declined, and the other non-labor components are plateauing. A detailed methodology for rebasing the clinical service components of the RHC rate can be found in the Abt Hospice Study Technical Report which is published with this proposed rule at *http://www.cms.gov/Center/Provider-Type/Hospice-Center.html*.

Using the methodology described above, the rebased amount for FY 2011 would be $130.54 as described in Table 7 below.

[4] The original RHC rate in 1983 was $46.25. The FY 2011 rate for RHC was $146.63. $146.63/46.25 = 3.1704.

TABLE 7—COMPARISON OF RHC RATE COST COMPONENTS FROM 1983 TO FY 2011

RHC components	1983 Final rule cost per day	Inflation factor	FY 2011 Cost per day
Nursing Care	$16.25	N/A	$56.54
Home Health Aide	12.74	N/A	19.24
Social Services/Therapy	3.23	N/A	10.29
Home respite	1.46	× 3.1704	4.63
Interdisciplinary group	2.78	× 3.1704	8.81
Drugs	1.18	× 3.1704	3.74
Supplies	4.49	× 3.1704	14.23
Equipment	1.13	× 3.1704	3.58
Outpatient Hospital Therapies	2.99	× 3.1704	9.48
Total	46.25		130.54

Source: 1983 Final Rule and FY 2011 hospice cost report and claims data.

Note(s): The costs per day for the clinical services components (nursing care, home health aide and social services/therapy) were calculated based on the cost per minute for each discipline using cost report data multiplied by the RHC minutes for each discipline per RHC day from claims data to compute the cost of a discipline per RHC day. The average cost per day across all hospices in our sample was weighted by the number of RHC days. Of the 2,717 FY 2011 hospice cost reports for freestanding and facility-based hospices that were matched to FY 2011 claims data, we excluded: (1) cost reports with period less than 10 months or greater than 14 months; (2) cost reports with missing information or negative reported values for total costs or payments; (3) providers in the highest and lowest percentile (1% and 99%) in costs per days across all levels of care; (4) the top and bottom 5% of provider margin; and (5) providers were excluded if the log payment to cost ratio was greater than the 90th or less than the 10th percentile of this value across all providers plus or minus 1.5 times the range between the 10th and 90th percentiles of this log ratio. The number of hospices remaining in our sample was 2,140 representing 73.1 percent of RHC days in 2011.

For example, if we were to apply the rebased amounts for the clinical services components of RHC to FY 2014, we would inflate the FY 2011 rebased amount to FY 2013 levels. We first inflated the FY 2011 rebased rate by full hospital market basket of 3.0 percent for FY 2012. The FY 2012 rebased rate would be $134.46 ($130.54 × 1.03=$134.46). We then inflated the FY 2012 rebased rate by full hospital market basket of 2.6 percent for FY 2013. The FY 2013 rebased rate would be $137.96 ($134.46 × 1.026= $137.96). Finally, we inflated the rebased FY 2013 rate ($137.96) by applying the proposed hospice payment update percentage of 1.8 percent to calculate a FY 2014 rebased RHC rate. Therefore, the FY 2014 rebased rate would be $140.44, a 10.1 percent reduction in the FY 2014 proposed RHC payment rate of $156.21, or an estimated reduction in payments to hospices of $1.6 billion in FY 2014. Rebasing the clinical service components of the RHC payment is one of several approaches to hospice payment reform that CMS could consider for revising the RHC payment rate. As outlined in the Affordable Care Act, hospice payment reform must be done in a budget neutral manner. As rebasing would be considered part of hospice payment reform, any savings achieved through the reduction of the RHC rate would need to be redistributed in a budget neutral manner.

b. Site of Service Adjustment for Hospice Patients in Nursing Facilities

As part of future hospice payment reform, we are considering an OIG recommendation to reduce payments to Medicare hospices for beneficiaries in nursing facilities who are receiving hospice care. The OIG's July 2011 report entitled ''Medicare Hospices that Focus on Nursing Facility Residents,'' (available at *https://oig.hhs.gov/oei/reports/oei-02–10–00070.pdf*) studied hospice patients in nursing facilities. This report noted the growth of hospice services provided to beneficiaries in nursing facilities, and discussed hospices that have a high percentage of their beneficiaries in nursing facilities. The OIG's report noted that the current payment structure provides incentives for hospices to seek out beneficiaries in nursing facilities, as these beneficiaries often receive longer but less complex care. The OIG noted that unlike private homes, nursing facilities are staffed with professional caregivers and are often paid by third-party payers, such as Medicaid. These facilities are required to provide personal care services, which are similar to hospice aide services that are paid for under the hospice benefit. To lessen this incentive, the OIG recommended that we reduce Medicare payments for hospice care provided in nursing facilities.

In addition, the March 2012 Medicare Payment Advisory Commission (MedPAC) report entitled ''Report to Congress: Medicare Payment Policy'' noted that hospices with a higher share of their patients in nursing facilities have margins as high as 13.8 percent (pages 302 and 303). MedPAC attributed these higher margins to possible efficiencies in the nursing home setting (multiple patients in a single setting, reduced driving time and mileage), and to reduced workload due to an overlap in aide services and supplies provided by the nursing facility.

In response to both MedPAC's and OIG's concerns about possible duplication of aide services provided both by the hospice and the nursing facility, we conducted an analysis of the number and length of aide visits per day using 2011 hospice claims data. Table 8 below describes the number and length of aide visits for RHC beneficiaries at home (including patients in an assisted living facility) compared to RHC beneficiaries in a NF or SNF.

TABLE 8—HOSPICE ROUTINE HOME CARE AIDE SERVICES 2011

	Sites of service		Difference	
	Home Q5001/2	NF/SNF Q5003/4	NF/SNF–Home	%
Number of beneficiaries	769,640	302,004	(467,636)	
Total days	58,637,171	22,946,972	(35,690,199)	
Total visits	16,625,635	8,501,366	(8,124,269)	
Total minutes	1,223,254,095	584,825,520	(638,428,575)	

TABLE 8—HOSPICE ROUTINE HOME CARE AIDE SERVICES 2011—Continued

	Sites of service		Difference	
	Home Q5001/2	NF/SNF Q5003/4	NF/SNF–Home	%
Visits per beneficiary	21.6	28.1	6.5	30.3
Minutes per visit	73.6	68.8	(4.8)	6.5
Total visits/day	0.28	0.37	0.09	30.7
Total minutes/day	20.86	25.49	4.62	22.2

Source: Abt Associates Hospice Claims Data File, 2011.

Table 8 demonstrates that hospice patients in a NF/SNF receive more visits than patients at home, though the length of those visits is shorter. Average minutes per day shows that RHC patients in a NF/SNF had hospice aide services of longer duration (25.49 minutes) than RHC patients at home (20.86 minutes). The Medicare Conditions of Participation (CoPs) require that hospices provide services at the same level and to the same extent as those services would be provided if the NF/SNF resident were in his or her home. Hospices provide aide services to beneficiaries at home depending on the beneficiaries' needs. It seems reasonable to expect that a beneficiary who has a paid caregiver (that is, a NF/SNF aide) does not need as many services from the hospice aide, because those services are being provided by the paid caregiver. As described in the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32095), ''[h]ospice care is meant to supplement the care provided by the patient's caregiver.'' Given the presence of the paid caregiver in the NF/SNF, we would expect that on average, there would be *fewer* hospice aide services provided to hospice patients in a NF/SNF than to hospice patients at home.

It is not clear why hospice patients in nursing facilities are receiving more minutes per day of aide services than hospice patients at home. We used regression analysis to control for age, gender, diagnosis, length of stay, and provider characteristics (ownership status, base, size, age of hospice, geographic location) when analyzing the visit data. However, we still found that significantly more aide services were provided to NF/SNF patients than to patients at home, even after controlling for patient and provider characteristics.

The June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088) preamble details the requirements related to aide services provided to hospice patients residing in a nursing facility. These requirements can also be found at § 418.112(c)(4) through (5). The CoPs require a written agreement between the hospice and NF/SNF, which specifies that the NF/SNF should continue to provide the aide services that are provided prior to the hospice election, to meet the patient's needs at that same level of care as if the patient were at home. These services include providing 24 hour room and board care, meeting the patient's personal care needs, and to the degree permitted by State law, administering medications or therapies. There should be no reduction of NF/SNF aide services to a patient in anticipation of a future hospice election, or once the patient (or his/her representative) elects the hospice benefit. As such, hospice patients in nursing facilities should have much, if not most, of their need for aide services provided by the facility's aide. As stated previously, we would expect that, on average, the hospice aide would be providing fewer services to nursing facility patients than to patients at home.

Table 8 suggests that the hospice aide may be replacing the facility aide, rather than supplementing or augmenting the care of the facility aide. Or, as the OIG and MedPAC identified, there could be an overlap in aide services when a hospice beneficiary is in a NF/SNF. It would not be appropriate for the Medicare hospice benefit to subsidize the nursing home benefit by providing aide services that the facility aide should provide. Section 1862(a)(1)(C) of the Social Security Act (the Act) forbids payment for any items or services which are not reasonable and necessary for the palliation and management of the terminal illness. Services which are not needed, or which are duplicative of those to be provided by the facility aide, would not be reasonable and necessary.

At this time, we are not proposing to make a site of service adjustment to reduce payments for RHC patients in a nursing facility. Any reform option considering reduced payments for RHC care provided to hospice patients in a NF or SNF should not result in a reduction in the services that hospice patients in NFs or SNFs receive, but would instead be a shifting of who provides those aide services; some of the services currently provided by the hospice aide would be provided by the facility aide as expected. As such, we do not expect that the quality of care to hospice patients in a NF/SNF would be diminished. If such a policy were to be proposed and implemented, it would be made in a budget neutral manner as required by the Affordable Care Act. In addition, we would monitor for any unintended consequences.

2. Reform Research Findings

We have conducted a number of analyses to better understand hospice utilization and trends, to identify vulnerabilities in the payment system, and to develop and test models that would more accurately match hospice resource use with Medicare payments. We posted the Abt Hospice Study Technical Report on hospice payment reform on our hospice center Web page, located at: *http://www.cms.gov/Center/Provider-Type/Hospice-Center.html*. The report summarizes research findings related to resource use and payment system vulnerabilities.

The report also includes a discussion of hospice cost report analyses. Overall, the total cost per election period has not significantly increased from 2007 to 2010, in real dollars. Inpatient costs constitute about 14 percent of hospice costs across freestanding hospice providers that reported inpatient costs. About one-third of providers reported no inpatient costs. It appeared that some providers with no inpatient costs were substituting continuous home care (CHC) for GIP, based on analysis of the proportion of CHC days. Visiting services (for example, direct labor costs for nurses, aides, social workers, counselors, and therapists) account for about two-thirds of hospice costs, and have trended upward from 2004 to 2010. Nursing care, hospice aides, and medical social services comprise 90 percent of visiting service costs.

Other hospice service costs include non-labor costs such as drugs, durable medical equipment (DME), supplies, imaging, patient transportation, and outpatient services. These types of services represent about 20 to 25 percent of total hospice costs. Drugs, DME, and supplies account for 90

percent of these other hospice services costs. Drug costs have trended downward over time, while medical supply costs have remained steady. Finally, in examining non-reimbursable costs, we found that 26 percent of providers in 2010 showed no bereavement costs on their cost report, even though bereavement services are required by statute; it is unclear if bereavement services were not provided or if bereavement costs were not correctly reported.

The report also describes an analysis of GIP utilization. In 2010 through 2011, a quarter of all hospice beneficiaries had at least one GIP stay, with a quarter of those stays associated with cancer diagnoses. While most GIP stays were 2 days long, the average GIP length of stay was 5.66 days, reflecting a small number of extremely long GIP stays. Sixty-five percent of GIP stays were provided in a hospice inpatient unit. Almost 80 percent of hospices provided at least one GIP day in 2010 through 2011. Hospices that provided GIP tended to be older and larger.

The Abt Hospice Study Technical Report also provides descriptive statistics for all beneficiaries and for 3 major sites of routine home care services. It includes visit data findings, including visits per day, visits per beneficiary, minutes per day, and minutes per beneficiary for key disciplines reported on hospice claims. Additionally, there are several figures which depict the U-shaped curve for key personnel by length of stay. The curves show that resource use tends to follow a U-shaped curve, but one which is higher at the beginning rather than at the end of the hospice stay. There was little evidence that strong differences in the U-shape exist across most subgroups (for example, freestanding vs. provider-based, ownership status, patient diagnosis).

For more detailed information on these findings, and a description of the methods used, see the Abt Hospice Study Technical Report, which is posted on the hospice center Web page (*http://www.cms.gov/Center/Provider-Type/Hospice-Center.html*). We have also posted a review of pertinent hospice literature as of December 2012 on the hospice center Web page. This should be considered an evolving document, as Abt Associates updates the review periodically. We encourage interested stakeholders to review this update on our progress. We will continue to collaborate with other federal experts regarding hospice payment reform research efforts and to update stakeholders on our progress on hospice payment reform.

3. Additional Data Collection

Over the past several years, MedPAC, the Government Accountability Office (GAO), and the HHS Office of Inspector General (OIG) have also recommended that we collect more comprehensive data in order to better understand the utilization of the Medicare hospice benefit. In December 2012, we posted a document to our Hospice Center Web page (*http://www.cms.gov/Center/Provider-Type/Hospice-Center.html*) describing additional data collection which we are considering, and noting that cost report revisions are forthcoming. We received 65 comments about the claims data collection items under consideration, which are briefly summarized below.

- *Line item visit data, including length of visit in 15-minute increments, for hospice chaplains and counselors providing care to hospice beneficiaries.* Commenters were supportive, but suggested we include phone calls by chaplains and counselors, and allow reporting of chaplain time spent officiating or attending beneficiary funerals, as this is part of their service to families. A few suggested that we have a separate category for Bereavement Counseling to acknowledge this requirement even if it is not subject to reimbursement. Several suggested we define ''other counselors.''
- *Line item visit data, including length of visits in 15-minute increments, for hospice staff providing care to hospice patients receiving GIP in a hospital or nursing facility, but not for hospice patients receiving GIP in a hospice facility.* Our suggestion to collect GIP visit data did not include visits by non-hospice staff, and was focused on patients in a hospital or nursing facility only. Therefore, GIP visits to hospice patients in hospice inpatient facilities continue to be reported as weekly totals, without including the length of visits. Commenters were generally supportive, provided the visits were for hospice staff only. Several comments noted that this would be no more difficult than what already occurs when recording visits to patients' homes.
- *The National Provider Identifier (NPI) of facilities where hospice patients are receiving care.* Most commenters noted that it would not be difficult to get this information and enter it into their systems. A few commenters noted that sometimes patients are in more than one facility type during a claim period, but that there is only space for one NPI on the claim.
- *Post-mortem visits on the calendar day of death.* Commenters suggested we collect visit data for various timeframes after the time of death, rather than the calendar day of death, since many deaths occur late at night. They suggested we clarify what we mean by time of death (time death actually occurs, or time the death is pronounced). Several commenters suggested we gather post-mortem visit data regardless of level of care or site of service.
- *Any durable medical equipment (DME) provided by the hospice.* Some commenters indicated that this would be difficult to collect and record on claims. Many indicated that DME suppliers bill them monthly, and waiting for the DME invoice would cause a delay in submission of their claims. They also noted that it would take a great deal of lead time to set this up with suppliers and software vendors to track DME at the patient level. A few suggested that we use aggregate data on DME costs from the cost reports instead.
- *Non-routine supplies provided by the hospice.* Most commenters indicated that this would be difficult to collect and record on claims. A number of commenters wrote that their software does not accommodate such reporting, and that it would create an additional burden on clinical staff to track these items. Several mentioned that it would take some lead time to modify existing systems to enable hospices to track and report this information accurately. A few suggested we use aggregate data on non-routine supplies from the cost reports instead.
- *Drugs (injectable, non-injectable, and over-the-counter) provided by the hospice.* Most commenters indicated that this would be difficult to collect and record on claims. Several asked if injectable drugs include infusion pumps, which is considered DME. Several commenters noted that the hospice staff person is not always the person administering drugs, making tracking more complicated; they suggested focusing on the fills, rather than drugs administered. Some wrote that hospices get their drugs from multiple pharmacies, making reporting more difficult due to inconsistencies in pharmacy billing. Others wrote that their data systems are not able to track drugs by patient, and suggested that we use aggregate data from the cost reports instead. Some noted that they purchase some drugs in larger quantities, making reporting at the patient level more complicated. A few noted that this could be done, but said that hospices would need lead time to prepare systems to track and report at the patient level. One suggested that we specify what cost structure drug charges

should be based upon, such as average wholesale price plus a percentage.

In summary, commenters were largely supportive of our suggestions to collect additional visit and NPI data on claims. Many suggested collecting data on DME, supplies, and drugs from the cost reports, rather than at the patient level. Several commenters reminded us that their primary focus is patient care, and were concerned about the cost of such data collection. We appreciate the comments submitted, and will consider this input as we move forward towards implementing any new data collection for hospices. We expect to issue a change request detailing the upcoming data collection this spring or summer.

Section 3132(a)(1)(C) of the Affordable Care Act also authorizes us to collect more data on hospice cost reports. The revisions to the hospice cost report and its associated instructions will be described in detail in a revision to the information collection request currently approved under OMB control number 0938–0758. As required by the Paperwork Reduction Act, we will publish the both 60-day and 30-day notices with comment periods in the **Federal Register** in the near future. Comments related to cost report revisions should be submitted as instructed in 60-day and 30-day notices that publish in the **Federal Register**.

E. Technical and Clarifying Regulations Text Change

We are proposing to incorporate the following technical change to correct an erroneous cross reference in our regulations text.

Administrative Appeals (§ 418.311)

A hospice that does not believe its payments have been properly determined may request a review from the intermediary or from the Provider Reimbursement Review Board (PRRB), depending on the amount in controversy. Section 418.311 details the procedures for appealing a payment decision and also refers to 42 CFR part 405, subpart R. The rationale for this appeals process was explained in the August 22, 1983 Hospice proposed rule (48 FR 38146) and finalized in the December 16, 1983 Hospice final rule (48 FR 56008). Hospices are permitted to appeal computation of the payment limit or the amount due to the hospice to the PRRB if the amount in controversy is $10,000 or more.

We propose to make a technical correction in § 418.311 to correct an erroneous reference to § 405.1874. The published reference to § 405.1874 does not exist and was a typographic error. We are correcting this error by changing the referenced § 405.1874 to § 405.1875—Administrator review. Section 405.1875 allows for the Administrator, at his or her discretion, to immediately review any decision of the Board as described in the August 22, 1983 proposed and December 16, 1983 final rules (48 FR 38159, and 48 FR 56019, respectively).

IV. Collection of Information Requirements

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. We are soliciting public comment on each of these issues for this section of this document that contains information collection requirements (ICRs).

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Under section 1814(i)(5)(D)(iii) of the Act, the Secretary must publish selected measures that will be applicable with respect to FY 2014 not later than October 1, 2012. In implementing the Hospice quality reporting program, we seek to collect measure information with as little burden to the providers as possible and which reflects the full spectrum of quality performance.

We propose to implement a Hospice Experience of Care Survey to reflect the patients' families' and friends' perspectives of care in hospices. The 60-day notice for the field test of the survey was published on April 4, 2013 (78 FR 20323) under CMS–10475 (OCN 0938-New). While we set out the requirements and burden estimates for the field study, it is too early to set out the requirements and burden estimates for the national implementation of the survey. We anticipate having the final survey instrument in 2014 and setting out the collection of information requirements and burden estimates in the proposed rule for CY 2015. We propose implementation of the survey in 2015.

In the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47302, 47320), to meet the quality reporting requirements for hospices for the FY 2014 payment determination as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures: (1) An NQF-endorsed measure that is related to pain management, NQF #0209; and (2) a structural measure that is not endorsed by NQF: Participation in a Quality Assessment and Performance Improvement (QAPI) program that includes at least three quality indicators related to patient care. In this rule, we propose that the structural measure related to QAPI indicators and the NQF #0209 pain measure not be required for the hospice quality reporting program beyond data submission for the FY 2015 payment determination.

We are not proposing to adopt any new measures in this proposed rule. However, we are proposing to implement a hospice patient-level data set to be used by all hospices to collect and submit standardized data about each patient admitted to hospice. This Hospice Item Set will be used to support the standardized collection and calculation of quality measures, collection of the requisite data elements. Hospices would be required to complete and submit an admission HIS and a discharge HIS on all patients admitted to hospice starting July 1, 2014 for FY 2016 APU determination. The admission and discharge HIS will collect the standardized data elements needed to calculate 7 NQF endorsed measures for hospice.

Using 2011 Medicare claims data we have estimated that there will be approximately 1,089,719 admissions across all hospices per year and therefore, we would expect that there should be 1,089,719 Hospice Item Sets (consisting of one admission and one discharge assessment per patient), submitted across all hospices yearly. There were 3,742 certified hospices in the U.S. as of October 1, 2012; we estimate that each individual hospice will submit on average 291 Hospice Item Sets annually or 24 Hospice Items Sets per month.

The Hospice Item Set consists of both an admission assessment and a discharge assessment. As noted above, we estimate that there will be 1,089,719

hospice admissions across all hospices per year. Therefore, we expect there to be 2,179,438 Hospice Item Set submissions, (both admission and discharge assessment) submitted across all hospices annually or 181,620 across all hospices monthly. We further estimate that there will be 582 Hospice Item Set submissions by each hospice annually or 49 submissions monthly.

For the Admission Hospice Item Set, we estimate that it will take 14 minutes of time by a clinician such as a Registered Nurse at an hourly wage of $33.23 to abstract data for Admission Hospice Item Set. This would cost the facility approximately $7.75 for each admission assessment.[5] We further estimate that it will take 5 minutes of time by clerical or administrative staff person such as a medical data entry clerk or medical secretary at an hourly wage of $15.59 to upload the Hospice Item Set data into the CMS system. This would cost the facility approximately $1.30 per assessment.[6] For the Discharge Hospice Item Set, we estimate that it will take 5 minutes of time by a clinician such as a nurse at an hourly wage of $33.23 to abstract data for Discharge Hospice Item Set. This would cost the facility approximately $2.77. We further estimate that it will take 5 minutes of time by clerical or administrative staff such as a medical data entry clerk or medical secretary at an hourly wage of $15.59 to upload data into the CMS system. This would cost the facility approximately $1.30.

We estimate that the total nursing time required for completion of both the admission and discharge assessments is 19 minutes at a rate of $33.23 per hour. The annualized cost across all Hospices for the nursing/clinical time required to complete both the admission and discharge Hospice Item sets is estimated to be $11,458,528 and the cost to each individual Hospice is estimated to be $3,062.14. The estimated time burden to hospices for a medical data entry clerk to complete the admission and discharge Hospice Item Set assessments is 10 minutes at a rate of $15.59 per hour. The cost for completion of the both the admission and discharge Hospice Item sets by a medical data entry clerk is estimated to be $2,829,401 across all Hospices and $756.12 to each Hospice.

The total combined time burden for completion of the Admission and Discharge Hospice Data Item Sets is estimated to be 29 minutes. The total annualized cost across all hospices is estimated to be $14,287,929. For each individual hospice, this annualized cost is estimated to be $3,818.26. The estimated cost for each individual Hospice Item Set submission is $13.11.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS–1449–P]

Fax: (202) 395 6974; or

Email: *OIRA_submission@omb.eop.gov*

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule follows § 418.306(c) which requires annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Metropolitan Statistical Areas (MSAs). This rule proposes updates to the hospice payment rates for FY 2014. In addition, this proposed rule provides background on hospice care, clarifies diagnosis coding on hospice claims, updates the public on the status of hospice payment reform, proposes a technical and clarifying regulatory text change, and proposes changes to the hospice quality reporting program.

B. Overall Impact

The overall impact of this proposed rule is an estimated net increase in Federal payments to hospices of $180 million, or 1.1 percent, for FY 2014. This estimated impact on hospices is a result of the proposed hospice payment update percentage for FY 2014 of 1.8 percent and changes to the FY 2014 hospice wage index, including a reduction to the BNAF by an additional 15 percent, for a total BNAF reduction of 70 percent (10 percent in FY 2010, and 15 percent per year for FY 2011 through FY 2014). A 70 percent reduced BNAF is computed to be 0.018449 (or 1.8449 percent). The BNAF reduction is part of a 7-year BNAF phase-out that was finalized in in the August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39384), and is not a policy change.

1. Detailed Economic Analysis

Column 4 of Table 9 shows the combined effects of the updated wage data (the 2012 pre-floor, pre-reclassified hospital wage index) and of the additional 15 percent reduction in the BNAF (for a total BNAF reduction of 70 percent), comparing estimated payments for FY 2013 to estimated payments for FY 2014. The FY 2013 payments used for comparison have a 55 percent reduced BNAF applied. We estimate that the total hospice payments for FY 2014 would decrease by 0.7 percent. This 0.7 percent is the result of a 0.1 percent reduction due to the use of updated wage data ($ − 20 million), and a 0.6 percent reduction due to the additional 15 percent reduction in the BNAF ($ − 100 million). This estimate does not take into account the proposed hospice payment update percentage of 1.8 percent (+$300 million) for FY 2014.

Column 5 of Table 9 shows the combined effects of the updated wage data (the 2012 pre-floor, pre-reclassified hospital wage index), the additional 15 percent reduction in the BNAF (for a total BNAF reduction of 70 percent), and the proposed hospice payment update percentage of 1.8 percent. The proposed 1.8 percent hospice payment update percentage is based on a 2.5 percent estimated inpatient hospital market basket update for FY 2014 reduced by a 0.4 percentage point productivity adjustment and by 0.3 percentage point as mandated by the Affordable Care Act. The estimated effect of the 1.8 percent proposed hospice payment update percentage is an increase in payments to hospices of approximately $300 million. Taking into account the 1.8 percent proposed hospice payment update percentage (+$300 million), the use of updated wage data ($ − 20 million), and the additional 15 percent reduction in the BNAF ($ − 100 million), it is estimated that hospice payments would increase by $180 million in FY 2014 ($300 million − $20 million − $100 million = $180 million) or 1.1 percent in FY 2014.

[5] 14 minutes of time by a Registered Nurse at $33.23/60 minutes per hour = $0.56; $0.56 per one minute × 5 minutes = $7.75.

[6] 5 minutes of time by a Medical Data Entry Clerk at $15.59/60 minutes per hour = $0.265; $0.265 per one minute × 5 minutes = $1.30.

a. Effects on Hospices

This section discusses the impact of the projected effects of the hospice wage index and the effects of a proposed 1.8 percent hospice payment update percentage for FY 2014. This proposed rule continues to use the CBSA-based pre-floor, pre-reclassified hospital wage index as a basis for the hospice wage index and continues to use the same policies for treatment of areas (rural and urban) without hospital wage data. The proposed FY 2014 hospice wage index is based upon the 2012 pre-floor, pre-reclassified hospital wage index and the most complete claims data available (FY 2012) with an additional 15 percent reduction in the BNAF (for a total BNAF reduction of 70 percent).

For the purposes of our impacts, our baseline is estimated FY 2013 payments with a 55 percent BNAF reduction, using the 2011 pre-floor, pre-reclassified hospital wage index. Our first comparison (column 3 of Table 9) compares our baseline to estimated FY 2014 payments (holding payment rates constant) using the updated wage data (2012 pre-floor, pre-reclassified hospital wage index). Consequently, the estimated effects illustrated in column 3 of Table 9 show the distributional effects of the updated wage data only. The effects of using the updated wage data combined with the additional 15 percent reduction in the BNAF are illustrated in column 4 of Table 9.

We have included a comparison of the combined effects of the additional 15 percent BNAF reduction, the updated wage data, and the proposed 1.8 percent hospice payment update percentage for FY 2014 (Table 9, column 5). Presenting these data gives the hospice industry a more complete picture of the effects on their total revenue based on changes to the hospice wage index and the BNAF phase-out as discussed in this proposed rule and the proposed FY 2014 hospice payment update percentage. Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

TABLE 9—ANTICIPATED IMPACT ON MEDICARE HOSPICE PAYMENTS OF UPDATING THE PRE-FLOOR, PRE-RECLASSIFIED HOSPITAL WAGE INDEX DATA, REDUCING THE BUDGET NEUTRALITY ADJUSTMENT FACTOR (BNAF) BY AN ADDITIONAL 15 PERCENT (FOR A TOTAL BNAF REDUCTION OF 70 PERCENT) AND APPLYING A 1.8 PERCENT HOSPICE PAYMENT UPDATE PERCENTAGE, COMPARED TO THE FY 2013 HOSPICE WAGE INDEX WITH A 55 PERCENT BNAF REDUCTION

	Number of hospices	Number of routine home care days in thousands	Percent change in hospice payments due to FY2014 wage index change	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment and market basket update
	(1)	(2)	(3)	(4)	(5)
ALL HOSPICES	3,545	85,390	−0.1	−0.7	1.1
URBAN HOSPICES	2,575	74,784	−0.1	−0.7	1.1
RURAL HOSPICES	970	10,606	−0.2	−0.6	1.2
BY REGION—URBAN:					
NEW ENGLAND	129	2,780	1.0	0.4	2.2
MIDDLE ATLANTIC	247	8,018	0.0	−0.6	1.2
SOUTH ATLANTIC	376	16,441	−0.7	−1.3	0.5
EAST NORTH CENTRAL	334	11,435	0.0	−0.6	1.2
EAST SOUTH CENTRAL	154	4,332	−0.5	−1.0	0.8
WEST NORTH CENTRAL	195	4,627	0.4	−0.2	1.6
WEST SOUTH CENTRAL	514	9,894	−0.4	−1.0	0.8
MOUNTAIN	260	6,545	−0.8	−1.4	0.4
PACIFIC	331	9,432	0.9	0.3	2.1
OUTLYING	35	1,280	0.3	0.3	2.1
BY REGION—RURAL:					
NEW ENGLAND	24	232	−0.7	−1.4	0.4
MIDDLE ATLANTIC	42	563	−0.1	−0.7	1.1
SOUTH ATLANTIC	135	2,358	−0.3	−0.6	1.2
EAST NORTH CENTRAL	137	1,708	0.4	−0.2	1.6
EAST SOUTH CENTRAL	132	1,814	0.1	0.0	1.8
WEST NORTH CENTRAL	182	1,240	−0.9	−1.3	0.5
WEST SOUTH CENTRAL	175	1,537	−0.1	−0.2	1.6
MOUNTAIN	95	665	0.3	−0.1	1.7
PACIFIC	47	473	−2.2	−2.9	−1.1
OUTLYING	1	15	0.0	0.0	1.8
BY SIZE/DAYS:					
0–3499 DAYS (small)	587	1,021	−0.4	−0.9	0.9
3500–19,999 DAYS (medium)	1,711	17,331	−0.2	−0.7	1.1
20,000+ DAYS (large)	1,247	67,037	−0.1	−0.7	1.1
TYPE OF OWNERSHIP:					
VOLUNTARY	1,077	30,041	0.0	−0.6	1.2
GOVERNMENT	486	8,911	−0.1	−0.7	1.1
PROPRIETARY	1,982	46,438	−0.2	−0.8	1.0
HOSPICE BASE:					

TABLE 9—ANTICIPATED IMPACT ON MEDICARE HOSPICE PAYMENTS OF UPDATING THE PRE-FLOOR, PRE-RECLASSIFIED HOSPITAL WAGE INDEX DATA, REDUCING THE BUDGET NEUTRALITY ADJUSTMENT FACTOR (BNAF) BY AN ADDITIONAL 15 PERCENT (FOR A TOTAL BNAF REDUCTION OF 70 PERCENT) AND APPLYING A 1.8 PERCENT HOSPICE PAYMENT UPDATE PERCENTAGE, COMPARED TO THE FY 2013 HOSPICE WAGE INDEX WITH A 55 PERCENT BNAF REDUCTION—Continued

	Number of hospices	Number of routine home care days in thousands	Percent change in hospice payments due to FY2014 wage index change	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment	Percent change in hospice payments due to wage index change, additional 15% reduction in budget neutrality adjustment and market basket Update
	(1)	(2)	(3)	(4)	(5)
FREESTANDING	2,547	69,752	−0.2	−0.8	1.0
HOME HEALTH AGENCY	521	9,848	0.3	−0.3	1.5
HOSPITAL	458	5,574	0.0	−0.6	1.2
SKILLED NURSING FACILITY	19	216	0.2	−0.5	1.3

Source: Providers with hospice claims with dates of service between October 1, 2011 and September 30, 2012, based on the 2012 standard analytic file (SAF) as of December 31, 2012.

Note: The proposed 1.8 percent hospice payment update percentage for FY 2014 is based on an estimated 2.5 percent inpatient hospital market basket update, reduced by a 0.4 percentage point productivity adjustment and by 0.3 percentage point. Starting with FY 2013 (and in subsequent fiscal years), the market basket percentage update under the hospice payment system as described in section 1814(i)(1)(C)(ii)(VII) or section 1814(i)(1)(C)(iii) of the Act will be annually reduced by changes in economy-wide productivity as set out at section 1886(b)(3)(B)(xi)(II) of the Act. In FY 2013 through FY 2019, the market basket percentage update under the hospice payment system will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions set out under section 1814(i)(1)(C)(v) of the Act).

REGION KEY:

NEW ENGLAND=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; MIDDLE ATLANTIC=Pennsylvania, New Jersey, New York; SOUTH ATLANTIC=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; EAST NORTH CENTRAL=Illinois, Indiana, Michigan, Ohio, Wisconsin; EAST SOUTH CENTRAL=Alabama, Kentucky, Mississippi, Tennessee; WEST NORTH CENTRAL=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; WEST SOUTH CENTRAL=Arkansas, Louisiana, Oklahoma, Texas; MOUNTAIN=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; PACIFIC=Alaska, California, Hawaii, Oregon, Washington; OUTLYING=Guam, Puerto Rico, Virgin Islands.

Table 9 shows the results of our analysis. In column 1, we indicate the number of hospices included in our analysis as of December 31, 2012, which had also filed claims in FY 2012. In column 2, we indicate the number of routine home care days that were included in our analysis, although the analysis was performed on all types of hospice care. Columns 3, 4, and 5 compare FY 2013 estimated payments with those estimated for FY 2014. The estimated FY 2013 payments incorporate a BNAF, which has been reduced by 55 percent. Column 3 shows the percentage change in estimated Medicare payments for FY 2014 due to the effects of the updated wage data only, compared with estimated FY 2013 payments. The effect of the updated wage data can vary from region to region depending on the fluctuations in the wage index values of the pre-floor, pre-reclassified hospital wage index. Column 4 shows the percentage change in estimated hospice payments from FY 2013 to FY 2014 due to the combined effects of using the updated wage data and reducing the BNAF by an additional 15 percent. Column 5 shows the percentage change in estimated hospice payments from FY 2013 to FY 2014 due to the combined effects of using updated wage data, an additional 15 percent BNAF reduction, and the proposed 1.8 percent hospice payment update percentage.

The impact of changes in this proposed rule has been analyzed according to the type of hospice, geographic location, type of ownership, hospice base, and size. Table 9 categorizes hospices by various geographic and hospice characteristics. The first row of data displays the aggregate result of the impact for all Medicare-certified hospices. The second and third rows of the table categorize hospices according to their geographic location (urban and rural). Our analysis indicated that there are 2,575 hospices located in urban areas and 970 hospices located in rural areas. The next two row groupings in the table indicate the number of hospices by census region, also broken down by urban and rural hospices. The next grouping shows the impact on hospices based on the size of the hospice's program. We determined that the majority of hospice payments are made at the routine home care rate. Therefore, we based the size of each individual hospice's program on the number of routine home care days provided in FY 2012. The next grouping shows the impact on hospices by type of ownership. The final grouping shows the impact on hospices defined by whether they are provider-based or freestanding.

As indicated in column 1 of Table 9, there are 3,545 hospices. Approximately 44.1 percent of Medicare-certified hospices are identified as voluntary (non-profit) or government agencies; a majority (55.9 percent) are proprietary (for-profit), with 1,563 designated as non-profit or government hospices, and 1,982 as proprietary. In addition, our analysis shows that most hospices are in urban areas and provide the vast majority of routine home care days, most hospices are medium-sized, and the vast majority of hospices are freestanding.

b. Hospice Size

Under the Medicare hospice benefit, hospices can provide four different levels of care. The majority of the days provided by a hospice are routine home care (RHC) days, representing about 97 percent of the services provided by a hospice. Therefore, the number of RHC days can be used as a proxy for the size of the hospice, that is, the more days of care provided, the larger the hospice. We currently use three size designations to present the impact analyses. The

three categories are—(1) small agencies having 0 to 3,499 RHC days; (2) medium agencies having 3,500 to 19,999 RHC days; and (3) large agencies having 20,000 or more RHC days. The FY 2014 updated wage data before any BNAF reduction are anticipated to decrease payments to large hospices by 0.1 percent, to medium hospices by 0.2 percent, and to small hospices by 0.4 percent (column 3), respectively. The updated wage data and the additional 15 percent BNAF reduction (for a total BNAF reduction of 70 percent) are anticipated to decrease estimated payments to small hospices by 0.9 percent, to medium hospices by 0.7 percent, and to large hospices by 0.7 percent (column 4). Finally, the updated wage data, the additional 15 percent BNAF reduction (for a total BNAF reduction of 70 percent), and the proposed 1.8 percent hospice payment update percentage are projected to increase estimated payments by 0.9 percent for small hospices, by 1.1 percent for medium hospices, and by 1.1 percent for large hospices (column 5).

c. Geographic Location

Column 3 of Table 9 shows the estimated impact of using updated wage data without the BNAF reduction. Urban hospices are anticipated to experience a decrease of 0.1 percent and rural hospices are anticipated to experience a decrease of 0.2 percent in payments. Urban hospices can anticipate an increase in payments in New England of 1.0 percent, in the West North Central region of 0.4 percent, in the Pacific region of 0.9 percent and in Outlying regions of 0.3 percent. Urban hospices can anticipate a decrease in payments ranging from 0.8 percent in the Mountain region to 0.4 percent in the West South Central region. Urban hospices in Middle Atlantic and East North Central are not anticipated to be affected by the updated wage data.

Rural hospices are estimated to see a decrease in payments in six regions, ranging from 2.2 percent in the Pacific region to 0.1 percent in the West South Central and Middle Atlantic regions. Rural hospices can anticipate an increase in payments in three regions ranging from 0.1 percent in the East South Central region to 0.4 percent in the East North Central region. There is no anticipated change in payments for Outlying regions due to the use of updated wage data.

Column 4 shows the combined effect of the updated wage data and the additional 15 percent BNAF reduction on estimated payments, as compared to the FY 2013 estimated payments using a BNAF with a 55 percent reduction. Overall, hospices are anticipated to experience a 0.7 percent decrease in payments, with urban hospices experiencing an estimated decrease of 0.7 percent and rural hospices experiencing an estimated decrease of 0.6 percent. All urban areas other than Outlying, Pacific and New England regions are estimated to see decreases in payments, ranging from 1.4 percent in the Mountain region to 0.2 percent in the West North Central region. Rural hospices are estimated to experience a decrease in payments in seven regions, ranging from 2.9 percent in the Pacific region to 0.1 percent in the Mountain region. Payments in the Outlying and East South Central regions are anticipated to stay relatively stable.

Column 5 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction, and the proposed 1.8 percent hospice payment update percentage on estimated FY 2014 payments as compared to estimated FY 2013 payments. Overall, hospices are anticipated to experience a 1.1 percent increase in payments, with urban hospices anticipated to experience a 1.1 percent increase in payments, and rural hospices anticipated to experience a 1.2 percent increase in payments. Urban hospices are anticipated to experience an increase in estimated payments in every region, ranging from 0.4 percent in the Mountain region to 2.2 percent in New England. Rural hospices in every region but one are estimated to see an increase in payments ranging from 0.4 percent in New England to 1.8 percent in the East South Central and Outlying regions. The Pacific region is estimated to see a decrease in payments of 1.1 percent.

d. Type of Ownership

Column 3 demonstrates the effect of the updated wage data on FY 2014 estimated payments, versus FY 2013 estimated payments. We anticipate that using the updated wage data would decrease estimated payments to proprietary (for-profit) and Government hospices by 0.2 percent and 0.1 percent, respectively. Voluntary (non-profit) hospices are expected to have no change in payments. Column 4 demonstrates the combined effects of the updated wage data and of the additional 15 percent BNAF reduction. Estimated payments to voluntary (non-profit), proprietary (for-profit) and government hospices are anticipated to decrease by 0.6 percent, 0.8 percent and 0.7 percent, respectively. Column 5 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction (for a total BNAF reduction of 70 percent), and the proposed 1.8 percent hospice payment update percentage on estimated payments, comparing FY 2014 to FY 2013. Estimated FY 2014 payments are anticipated to increase for voluntary (non-profit) hospices, for proprietary (for-profit) hospices, and government hospices, by 1.2, 1.0, and 1.1 percent, respectively.

e. Hospice Base

Column 3 demonstrates the effect of using the updated wage data, comparing estimated payments for FY 2014 to FY 2013. Estimated payments are anticipated to decrease for freestanding hospices by 0.2 percent. Estimated payments are anticipated to increase for Home Health Agency and Skilled Nursing Facility based hospices by 0.3 percent and by 0.2 percent, respectively. Hospital based hospices are estimated to experience no change in payments. Column 4 shows the combined effects of the updated wage data and reducing the BNAF by an additional 15 percent, comparing estimated payments for FY 2014 to FY 2013. All hospice facilities are anticipated to experience decrease in payments ranging from 0.8 percent for freestanding hospices to 0.3 percent for Home Health Agency based hospices. Column 5 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction, and the proposed 1.8 percent hospice payment update percentage on estimated payments, comparing FY 2014 to FY 2013. Estimated payments are anticipated to increase for all hospices, ranging from 1.0 percent for freestanding hospices to 1.5 percent for Home Health Agency based hospices.

f. Effects on Other Providers

This proposed rule only affects Medicare hospices, and therefore has no effect on other provider types.

g. Effects on the Medicare and Medicaid Programs

This proposed rule only affects Medicare hospices, and therefore has no effect on Medicaid programs. As described previously, estimated Medicare payments to hospices in FY 2014 are anticipated to decrease by $20 million due to the update in the wage index data, and to decrease by $100 million due to the additional 15 percent reduction in the BNAF (for a total 70 percent reduction in the BNAF). However, the proposed hospice payment update percentage of 1.8 percent is anticipated to increase Medicare payments by $300 million. Therefore, the total effect on Medicare

hospice payments is estimated to be a $180 million increase (1.1 percent).

h. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 10 below, we have prepared an accounting statement showing the classification of the expenditures associated with this proposed rule. Table 10 provides our best estimate of the increase in Medicare payments under the hospice benefit as a result of the changes presented in this proposed rule using data for 3,545 hospices in our database.

TABLE 10—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2013 TO FY 2014

[In $Millions]

Category	Transfers
Annualized Monetized Transfers.	$180.
From Whom to Whom	Federal Government to Hospices.

i. Conclusion

In conclusion, the overall effect of this proposed rule is an estimated $180 million increase in Federal Medicare payments to hospices due to the wage index changes (including the additional 15 percent reduction in the BNAF) and the proposed hospice payment update percentage of 1.8 percent. Furthermore, the Secretary has determined that this will not have a significant impact on a substantial number of small entities, or have a significant effect relative to section 1102(b) of the Act.

2. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all hospices 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 by meeting the Small Business Administration (SBA) definition of a small business (in the service sector, having revenues of less than $7.0 million to $34.5 million in any 1 year), or being nonprofit organizations. While the SBA does not define a size threshold in terms of annual revenues for hospices, it does define one for home health agencies ($14 million; see *http://www.sba.gov/sites/default/files/files/Size_Standards_Table(1).pdf*). For the purposes of this proposed rule, because the hospice benefit is a home-based benefit, we are applying the SBA definition of ''small'' for home health agencies to hospices; we will use this definition of ''small'' in determining if this proposed rule has a significant impact on a substantial number of small entities (for example, hospices). We estimate that 95 percent of hospices have Medicare revenues below $14 million or are nonprofit organizations and therefore are considered small entities.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if they reach a threshold of 3 to 5 percent or more of total revenue or total costs. As noted above, the combined effect of the updated wage data, the additional 15 percent BNAF reduction, and the proposed FY 2014 hospice payment update percentage of 1.8 percent results in an increase in estimated hospice payments of 1.1 percent for FY 2014. For small and medium hospices (as defined by routine home care days), the estimated effects on revenue when accounting for the updated wage data, the additional 15 percent BNAF reduction, and the proposed FY 2014 hospice payment update percentage reflect increases in payments of 0.9 percent and 1.1 percent, respectively. Therefore, the Secretary has determined that this proposed rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule only affects hospices. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $141 million or more.

VII. Federalism Analysis and Regulations Text

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or tribal governments.

List of Subjects in 42 CFR Part 418

Health Facilities, Hospice Care, Medicare, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 418 as set forth below:

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 418.311 [Amended]

■ 2. Amend § 418.311 by removing the reference to ''§ 405.1874'' and adding in its place the reference ''§ 405.1875''.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 23, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 25, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–10389 Filed 4–29–13; 4:15 pm]

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